REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	June 2008	

4. TITLE AND SUBTITLE
The Utility of the IsoBalance Force Platform in the Assessment of Balance: Mechanical and Human Subjects Testing

5. FUNDING NUMBERS

6. AUTHOR(S)
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Military Performance Division
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Natick, MA 01760-5007

8. PERFORMING ORGANIZATION REPORT NUMBER
T08-09

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
US Army Medical Research and Materiel Command
Fort Detrick
Frederick, MD 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; unlimited distribution

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

Medically expedient and evidence-based examination metrics that can be employed in a combat setting are needed to assist clinicians in identifying and classifying Soldiers who may have sustained mild Traumatic Brain Injury (mTBI). MRMC agreed to test the IsoBalance device for REF as an instrument to measure postural sway parameters potentially related to mTBI. USARIEM conducted mechanical tests in the laboratory as well as human standing balance tests to assess device utility, precision, and accuracy. Data were collected on over 500 healthy soldiers at Ft. Jackson, SC during January 2008 using a standard battery of standing balance tests for comparison to results from the open literature. Over 90% of the data collected were affected by an unexplained signal deviation (artifact) that had a profound effect on the results. Results not affected by artifact were plagued with issues of low data resolution and high variability when compared to similar results reported in the literature. Based on the results of the mechanical and human balance data presented in this report, and a separate letter of warning from the FDA (Appendix C), fielding of the IsoBalance system to assess postural sway in the classification of mTBI is not recommended at this time.

14. SUBJECT TERMS
Traumatic Brain Injuries (TBI); IsoBalance Platform; blast exposure; balance testing

15. NUMBER OF PAGES
55

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
UNCLASSIFIED	UNCLASSIFIED	UNCLASSIFIED	UL

USARIEM TECHNICAL REPORT T08-09

The Utility of the IsoBalance Force Platform in the Assessment of Balance: Mechanical and Human Subjects Testing

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BACKGROUND

The U.S. Army Vice-Chief of Staff directed the Rapid Equipping Force (REF) to collaborate with the Medical Research and Materiel Command (MRMC) to determine the utility of fielding the IsoBalance system as an adjunctive assessment device for Soldiers with mild traumatic brain injury (mTBI). The U.S. Army Research Institute of Environmental Medicine (USARIEM) was tasked to develop a study to determine the utility of the IsoBalance device in assessing postural sway and establish population-based normative data in healthy Soldiers.

ACKNOWLEDGEMENTS

The authors would like to thank the following individuals for their assistance in study design and planning, data collection, processing, and analysis, and feedback in preparing this technical report: Ms. Nancy Anderson, LTC Terri Campbell, LTC Sonja Corum, SGT Darnell Dobbins, Mr. Peter Frykman, SSG Samuel Griffin, SGT Scott Harris, Dr. Kristen Heaton, Dr. James McClung, Mr. Robert Mello, SPC Jay O'Hara, MSG Styer, SPC Tyson Tarr, SGT Lisa Trueheart, Ms. Leila Walker, MAJ Jennifer Walkanicz, and Dr. Kelly Williams.

EXECUTIVE SUMMARY

MRMC agreed to test the IsoBalance device for REF as an instrument to measure postural sway parameters potentially related to mild traumatic brain injury (mTBI). USARIEM conducted mechanical tests in the laboratory as well as human standing balance tests to assess device utility, precision, and accuracy. Data were collected on healthy soldiers at Ft. Jackson, SC during late January 2008 using a standard battery of standing balance tests for comparison to previous results published in the open literature. In addition, mechanical load magnitude and position standards were evaluated and monitored daily on 10 IsoBalance devices at Ft. Jackson during data collection, using methods developed at USARIEM.

Mechanical tests were performed on the IsoBalance units to determine measurement resolution for load magnitude and center of pressure position. Average variability for all mechanical tests was 241% (load) and 54% (position). Six of the 16 (38%) IsoBalance devices received by USARIEM were inoperable.

In IsoBalance recordings of 8 standing positions in 570 Soldiers (4966 measurements), over 90% of the data collected were affected by an unexplained signal deviation (artifact) that was non-biological in nature, yet had a profound effect on the data. Results not affected by artifact were plagued with issues of low data resolution and high variability when compared to similar results reported in the literature. Acceptable variability for such measures is < 10%. Data without artifact had variability estimates of 2% - 200%. Repeated tests to determine reliability yielded estimates ranging from 0.00 to 0.91. The standard for clinical measurements is > 0.90, and only one of 64 estimates (1.5%) met this criterion.

Based on the results of the mechanical and human balance data presented in this report, and a separate letter of warning from the FDA regarding marketing and manufacturing of a medical device (Warning Letter No. 2008-NOL-09, Appendix C of this report), fielding of the IsoBalance system to assess postural sway in the classification of mTBI is not recommended at this time.

INTRODUCTION

PROBLEM STATEMENT

The occurrence of traumatic brain injuries (TBI) has risen among U.S. military service members since the onset of the global war on terrorism. This increase is believed to be directly related to blast exposure due to combat scenarios encountered in theater by our deployed warfighters (e.g., via exposure to improvised explosive devices, or IEDs). Generally, TBI may be classified as mild, moderate, or severe according to the patient's symptoms, diagnostic imaging, and neurocognitive examination. However, there are no standardized guidelines for classification and a paucity of evidenced-based recommendations to support existing classification paradigms. Medically expedient and evidence-based examination metrics that can be employed in a combat setting are needed to assist clinicians in identifying and classifying Soldiers who may have sustained a mild TBI (mTBI).

Prevalence

Reports indicate that of the 1.5 million military members that have been deployed into a combat theater since 2001, more than 5500 individuals have sustained a TBI (3). Among combat casualties evacuated to Walter Reed Army Medical Center (WRAMC), 28% have been diagnosed with a TBI (22). However, these data may not capture the true magnitude of combat-related TBI as they reflect only personnel who have required evacuation for their injuries. Among 433 Soldiers with TBI evacuated to WRAMC, only 44% (190) were diagnosed with mTBI (22). The Department of Defense Working Group on mTBI has defined mTBI as "an injury to the brain resulting from an external force and/or acceleration/deceleration mechanism from an event such as a blast, fall, direct impact, or motor vehicle accident which causes an alteration in mental status typically resulting in the temporally related onset of symptoms such as: headache, nausea, vomiting, dizziness/balance problems, fatigue, insomnia/sleep disturbances, drowsiness, sensitivity to light/ noise, blurred vision, difficulty remembering, and/or difficulty concentrating (12)." This group has recommended that the decision to evacuate individuals with mTBI should be a function of the healthcare provider's initial and repeated assessments of the patient's status. It is believed that the occurrence of mTBI or concussion in theater may be under-reported due to lack of symptom reporting, failure to recognize symptoms in the context of more pronounced injury, or lack of necessity to evacuate personnel who are able to recover in a short period of time to higher echelons of medical care. Potential underreporting of mTBI was illustrated by Hoge et al. (13) who surveyed 2525 Soldiers 3 months after returning from combat in Iraq and stated that 15% of these Soldiers reported sustaining an mTBI using the DOD working group guidelines.

Rationale

Initial triage of personnel exposed to blast relies heavily on the patient's Glascow Coma Scale (GCS) rating to determine evacuation priority. The GCS is a 15 item Likert scale assessment of cognitive status in critically ill patients (21). The scale is scored between 3 and 15, with higher scores indicating greater cognitive status. Patients with higher GCS ratings (13-15) are generally equated with mTBI and may not require evacuation depending on comorbid injuries, additional symptoms and subsequent neurocognitive status (2). The Joint Theater Trauma Service has developed a clinical practice guideline and screening tool to assist Echelon I level healthcare providers with screening and referral of patients with suspected mTBI. This screening tool, the Military Acute Concussion Evaluation (MACE), rapidly assesses a patient's mental status, but only captures subjective complaints of altered functional status (i.e. dizziness, balance problems, and visual disturbances) (14). Since, in a combat environment, a soldier's functional and cognitive status parallel one another in carrying out mission requirements, it is necessary to develop field expedient test metrics which can differentiate normal from abnormal function in individuals who have sustained an mTBI.

One potentially useful metric is the assessment of balance in personnel who have sustained an mTBI. Balance is a key component of physical performance and an integral part of successful completion of complex physical tasks. Balance is most commonly assessed by postural sway, which is the amount of movement required by the body to maintain its center of mass (COM) within its base of support (BOS) during stance. Since it is often not practical to measure COM in a clinic or field setting, surrogates are used to measure stability. Measurement of postural sway under static conditions is commonly assessed using a force plate to measure changes in the center of pressure (COP). The COP is a composite measurement of changes in the COM and associated muscular forces acting against gravity to maintain the COM within the BOS (4) and has been highly correlated to COM measures (18, (23).

Multiple studies have demonstrated that balance and COP measurements are adversely affected following mTBI compared both to pre-injury scores and scores in healthy subjects (7, (8, (9, (10, (17, (19). Assessment of balance provides an objective, field expedient measurement of one component of function and may be an appropriate indicator of a soldier's physical ability to perform mission requirements.

Recently, a COP measurement system, the IsoBalance (IsoTechnology, Australia, http://isotechnology.net), was purchased under a department of Defense contract as for use a potential means of quantifying balance disturbance in soldiers with TBI. The U.S. Army Vice-Chief of Staff directed the Rapid Equipping Force to collaborate with the Medical Research and Materiel Command (MRMC) to determine the utility of fielding the IsoBalance system as an adjunctive assessment device for Soldiers with mTBI. The U.S. Army Research Institute of Environmental Medicine (USARIEM) was tasked to develop a study to determine the utility of the IsoBalance device in assessing postural sway and establish population-based normative data in healthy Soldiers.

METHODS

PURPOSE

The purposes of this study were to 1) assess the mechanical accuracy and precision of the IsoBalance system in recording axial force and COP position; and 2) collect postural sway data on young, healthy adults in order to establish a normative database of sway parameters in this population. Additionally, we sought to determine the test-retest reliability of the IsoBalance system in measuring postural sway in humans.

MECHANICAL TESTING

COP is calculated as the weighted average of all points of vertical force application on a force platform (11, 23). Therefore, it is essential to determine the capacity of any device measuring COP to accurately record the following:

1) Point of force applications within a reasonable area from the origin of the force plate.
2) The magnitudes of a physiologically relevant range of weights with respect to the population of interest.

For the purposes of our study, we defined a "reasonable area" as the surface area covered by a person standing in the static posture on the IsoBalance system wearing size 12 shoes, and "physiologically relevant weight" as a range of 75-300 lbs, to approximate the spectrum of personnel currently serving in the military.

System Testing

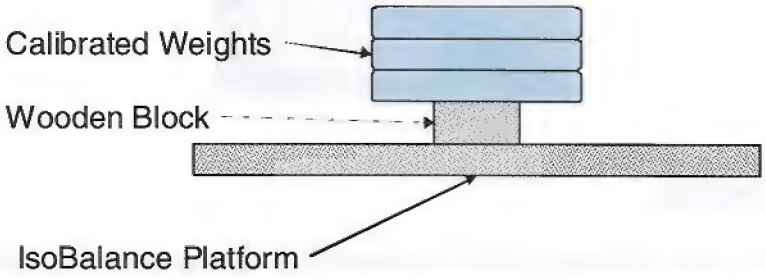
Based on preliminary tests conducted at the Center for Military Biomechanics on 4 of 16 units available (see Appendix B for details), two field expedient calibration tests were used to monitor and evaluate the mechanical performance of the ISOBALANCE systems. These tests, called the Load Test and the Point Test, are described in detail in the following sections.

Load Test

Three calibrated loads were measured on all platforms during each day of the study (Figure 1). These three loads were chosen because they could be easily obtained using standard 45-lb weight plates while capturing the physiological load characteristics of our sample (i.e., soldiers entering basic training). Two wooden interlocking 4 in x 4 in

x 10 in blocks were centered within marks on the platform during testing to allow convenient application and removal of the weights. Force plates were zeroed between each trial with the wooden blocks in place to negate the weight of the blocks. Once the force plate was zeroed, a known mass was applied to it using calibrated weights. A 30-sec. trial was then performed on the system with the load in place. Systems were incrementally loaded on successive trials with masses of 90.2, 134.4, and 179.1 lbs.

Figure 1. Graphic Depiction of the Load Test. Load Test: Weight was increased between trials, and the platform was "zeroed" between trials with the wooden block in place



Point Test

Based on preliminary tests (Appendix B), 5 points were chosen to test daily on all IsoBalance units used for field testing. Point #1 was noted as the origin marked on the IsoBalance platforms, and points 2-5 were located in each quadrant (exact dimensions given in Table 1). All calibration points were physically marked on all platforms in pencil and are indicated by the dots in Figure xxx. All points located within a 5-inch square surrounding the center of the plate and, like the Load Test (cap consistently throughout), were recorded on all platforms once per day during the entire study period (Figure 2). A common 4-ft garden stake (Home Depot item # 93169) was used to apply an axial load to the marked points by the same technician each day.

Table 1. Point Test Locations.

Point No	Point Measurements (with respect to platform origin)	
	X (in)	Y (in)
1	0	0
2	-3.75	3.75
3	3.75	3.75
4	-3.75	-3.75
5	3.75	-3.75

Figure 2. Point Test Administration. Approximate locations of points tested are indicated by dots in this figure; see text for further details

Human Subject Testing

10 personnel were trained on the operation of the IsoBalance during six 1-hour training sessions by a Research Biomechanist and Research Physical Therapist, both with experience in the use of force plates and balance testing.

570 U.S. Army Basic Training Soldiers (n = 285 men, 285 women), without a history of traumatic head injuries or acute lower extremity injuries, volunteered to participate in this study. In order to participate in the study, volunteers had to be 18 years of age or older, be on active duty status in the Army, be able to understand and read English, and have no prior diagnosis of traumatic brain injury (TBI). Potential volunteers were excluded if they were suffering from, recuperating from, or receiving treatment for a head injury. Individuals were also excluded if they currently had a lower extremity injury or other disorder that might adversely affect balance (i.e., vertigo, vestibular disorder, migraine, motion sickness, etc.), were suffering from acute or chronic sinus and/or ear infections, had a prior diagnosis of scoliosis or other spinal disorder, or had a prior diagnosis of a neurological or brain disorder. Subjects with abnormal balance tests (more than 2 SD from the mean) were excluded if they were taking medication that could potentially affect their balance (such as narcotics), or had sustained a previous head injury that resulted in loss of consciousness.

All volunteers were recruited from basic training or reception training units at Ft. Jackson, SC, over a 6-day period in January 2008. Prior to study inclusion, all volunteers were briefed on the study and then signed an informed consent document approved by the Human Use Research Committee at USARIEM. Volunteers were then asked to complete a brief questionnaire (Appendix A), and height and weight measurements were recorded. Volunteers then completed the IsoBalance testing. IsoBalance force plates were placed on a level floor in a climate controlled room on the ground level of the reception battalion at Ft. Jackson. Force plates were positioned

facing a wall approximately 18 inches from the front of the edge of the force plate. Volunteers stood on the force plate facing the wall in 8 different positions (Figure 3 a-h):

1) Bilateral stance eyes open (BSEO),
2) Bilateral stance eyes closed (BSEC),
3) Bilateral Stance Nodding head (BSNOD),
4) Bilateral Stance Shaking head (BSSHAKE),
5) Tandem Stance Left foot forward eyes open (TSLREO),
6) Tandem Stance Left foot forward eyes closed (TSLREC),
7) Tandem Stance Right foot forward eyes open (TSRLEO)
8) Tandem Stance Right foot forward eyes closed (TSRLEC?). Verify this acronym.

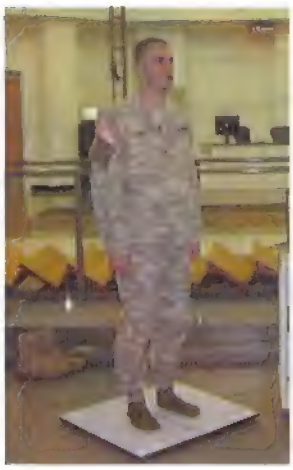
Rate of head movement during nodding and shaking the head was standardized by having subjects nod or shake their heads in time with a metronome set at 120 beats per minute. Each test lasted 30 sec, during which time volunteers were instructed to remain as still as possible and focus on a 5 in diameter circular target adjusted to eye-level. Total balance testing time per subject was approximately 10 min.

Eight measurement parameters of the IsoBalance were identified as variables of interest:

1) Percentage of time the subject's COP was maintained within an area 0.2 inches in diameter of the subject's mean COP (.2 in circle).
2) Percentage of time the subject's COP was maintained within an area 0.4 inches in diameter of the subject's mean COP (.4 in circle).
3) Percentage of time the subject's COP was maintained within an area 0.6 inches in diameter of the subject's mean COP (.6 in circle).
4) Total anterior/posterior and medial/lateral (A/P + M/L) excursion in inches (Total Travel).
5) Peak to Peak A/P COP displacement in inches (Dif x).
6) Peak to Peak M/L COP displacement in inches (Dif y).
7) Total A/P excursion in inches (Total Travel x).
8) Total M/L excursion in inches (Total Travel y).

In addition to the primary test battery, 33 volunteers (15 men and 18 women) were asked to repeat testing in each position 3 times to determine the test-retest reliability of the balance parameters assessed by the IsoBalance. Total balance testing time per subject for these individuals was approximately 25 min.

Figure 3. IsoBalance Platform test positions: a) Bilateral stance eyes open (BSEO); b) Bilateral stance eyes closed (BSEC); c) Bilateral Stance Nodding head (BSNOD); d) Bilateral Stance Shaking head (BSSHAKE); e) Tandem Stance Left foot forward eyes open (TSLREO); f) Tandem Stance Left foot forward eyes closed (TSLREC); g) Tandem Stance Right foot forward eyes open (TSRLEO); h) Tandem Stance Right foot forward eyes closed (TSRLEC)



a) BSEO

b) BSEC

c1) BSNOD

c2) BSNOD

d1) BSSHAKE

d2) BSSHAKE

e) TSLREO

f) TSLREC

g) TSRLEO

h) TSRLEC

Data Reduction and Statistical Analysis

Load Test. Difference scores between actual and system recorded measurements for the load test were calculated at each weight for each system on each day. Means, standard deviations (SD), and coefficients of variation (CV) of the difference scores were calculated to estimate how closely the system recordings approximated the actual loads used.

Point Test. Measured reference points were adjusted based on the mean location of point 1 (the platform origin). Difference scores between adjusted references (darker diamonds, Figure 4) and system recorded measurements for the point test were calculated at each position for each system on each day. Means, SD, and CV of the difference scores were calculated to estimate how closely the system recordings approximated the adjusted references.

Questionnaires. All volunteers were asked to complete a brief questionnaire that included information on demographics, branch of service, time in service, injury history and use of medications. Means, SD, and ranges were calculated for demographic data. Response frequencies were determined for injury history and medication use data. Separate Mann-Whitney U tests were performed to determine if differences in response rates between genders existed for any of the questionnaire variables. An alpha level of 0.05 was used to identify significant differences.

Artifact. Each IsoBalance measurement trace was visually inspected to determine whether or not the recording was free from signaling error not associated with postural sway. Randomly generated non-biological signaling error (artifact) was identified and its presence annotated to allow independent and comparative analyses of trials with and without artifact. The proportion of trials compromised by artifact was calculated separately for each position and each system, respectively. Additionally, the proportion of completed test batteries (all 8 test positions) containing artifact was calculated. Separate 95% confidence intervals (95% CI) of difference scores for proportions of artifact between each position were constructed to determine if the amount of artifact present for each position was statistically similar. This procedure was repeated for each system for individual trials and for completed test batteries.

Means, SD, ranges, CV, and 95% CI were calculated for each variable of interest for each position for trials with and without artifact, respectively. These values were also calculated for completed test batteries without artifact. Separate independent samples T-tests were calculated for each variable of interest in each position to determine if differences between trials with and without artifact existed. An alpha level of 0.05 was used to identify significant differences.

Reliability. Intraclass correlation coefficients (ICC) were calculated for subjects who completed repeated test batteries. The ICC is superior to traditional to estimates of correlation or indices of agreement, because it is based on an analysis of variance and therefore is able to demonstrate both relationship and magnitude of agreement between variables of interest in a single index (20). The ICC ranges from 0 to 1, with 0 indicating

no agreement and 1 indicating perfect agreement. An ICC which fails to reach significance suggests that the amount of variability associated with the point estimation of a particular variable is so great that repeated measurement estimates within that variable cannot be considered to be related. We employed a model 3 ICC; this is the appropriate statistic to assess the reliability of a single device across repeated testing. Three single trials of each position were compared (ICC 3,1).

Regression. Previous work with the IsoBalance (REF) recommended the use of a single test metric to stratify postural stability in Soldiers. It was suggested that the percentage of time the subject's COP was maintained within an area 0.6 inches in diameter of the subject's mean COP (.6 in circle) may be an appropriate metric to use to dichotomize postural stability into normal vs. abnormal, and an arbitrary cutoff of 94% was suggested as an appropriate criteria for differentiation in subjects tested with their eyes open. In order to test the assumption that the .6 in circle was representative of measures of postural sway (i.e., COP displacement or COP excursion), we performed univariate linear regression analyses using .6 in circle data as the dependent variable and displacement and excursion data, respectively, as independent variables.

RESULTS

16 IsoBalance systems were sent to USARIEM by REF. A single system was comprised of a carrying case, laptop computer, signal processing box, force plate, optical mouse, external hard drive, and 12 USB flash drives, as well as the associated power strips, cables, and cords to allow system connections. Six of these systems were found to be inoperable during their initial setup: four of the systems failed to run the IsoBalance software, one signal processing box failed to operate, and one force plate failed to pass a voltage safety test. An additional system failed to pass a calibration test during human subject testing and its use was terminated.

MECHANICAL TESTING

Load Test

Table 2 represents the aggregate results from the load test for all platforms across all days. The average confidence interval range of ± 2.9 lbs was considered acceptable. However, 11.6% of all recorded values (15/129) differed from their respective target weights by an average of ±16%, with deviations ranging from 11%-24%.

Table 2. Load Test Summary Statistics. Column Labeled "Target" Represents Actual Weight Of Calibrated Loads.

Target Weight (lbs.)	System Means (lbs)	Mean (SD) Difference from Target (lbs)	95% Confidence Interval (CI)			%CV
			lower		upper	
90.2	89.1	1.28 (3.5)	0.22	To	2.34	272
134.4	132.4	2.12 (6.1)	0.28	To	3.96	285
179.1	174.8	4.27 (10.43)	1.09	To	7.45	244

Point Test

Means, standard deviations, confidence intervals, and coefficients of variation for differences between adjusted reference points and measured averages for each point over all platforms and all days are presented in Table 3, and graphically in Figure 4. Overall, results indicated that the measurements taken at the origin (point 1) demonstrated the greatest amount of precision across platforms between days (mean difference 0.11 in; 95% CI 0.08 to 0.13 in). Away from the center of the platform, differences between recorded positions from their adjusted reference target ranged from 0.18 in. to 0.25 in. (95% CI range 0.08 in. to 0.33 in.). For points 2-5, a larger CI demonstrates that the position estimate is imprecise and could differ by as much as one-third of an inch for a force applied to an area of 4 mm (the tip of the garden stake).

Coefficients of variation (%CV) followed the same trend, with the lowest %CV being associated with the point closest to the center of the platform (28.7%, Table 3), and increasing for the points in each quadrant (44.9% to 78.7%). Lower %CV is associated with better performance, and acceptable limits for coefficients of variation in mechanical testing are typically below 15%.

Table 3. Differences Between Target Point (reference) and Observed Point Measurement From IsoBalance. Positions 1-5 Are Defined In Table 1; See Text For Details.

Point No. (Fig 5)	Mean (SD) Difference from Target (in)	95% Confidence Interval (CI)			%CV
		lower		upper	
1	0.11 (0.03)	0.08	to	0.13	28.7
2	0.18 (0.14)	0.08	to	0.28	78.7
3	0.24 (0.11)	0.16	to	0.31	44.9
4	0.20 (0.14)	0.09	to	0.30	73.4
5	0.25 (0.11)	0.17	to	0.33	44.5

Figure 4. Representation of the 5x5 inch calibration measurement square depicting the reference points (darker, filled diamond) and each system's daily average (open symbols), as well as a grand mean (lighter, filled diamond) for each point across all platforms and all days.

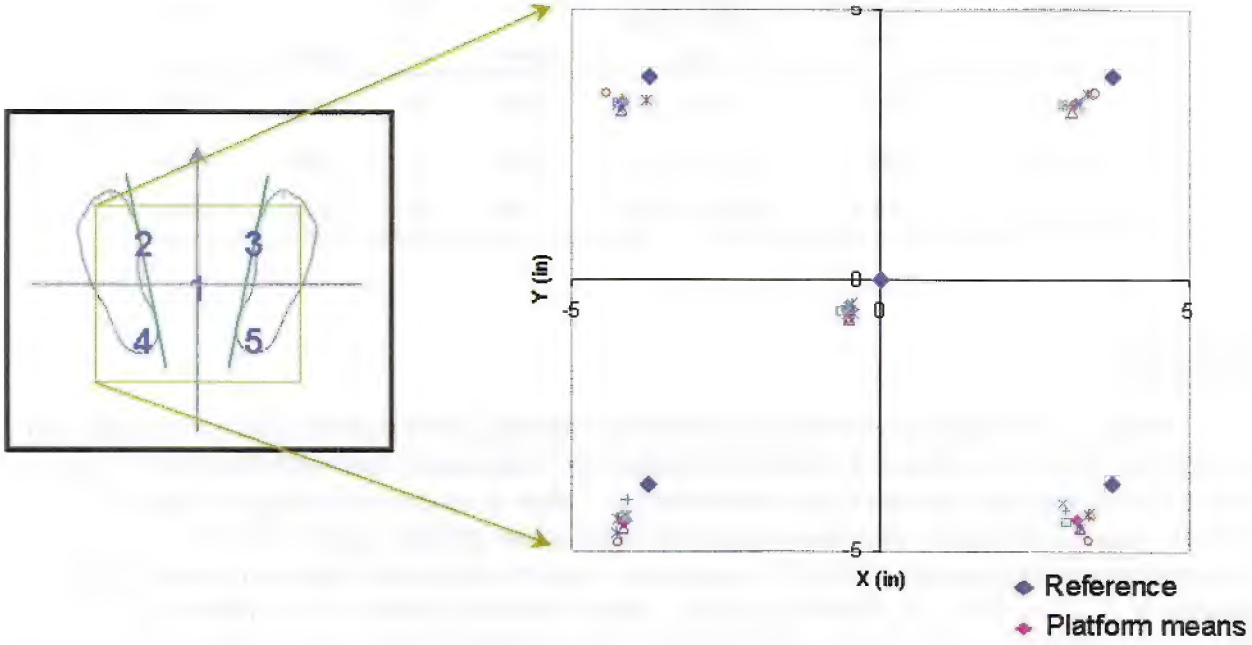
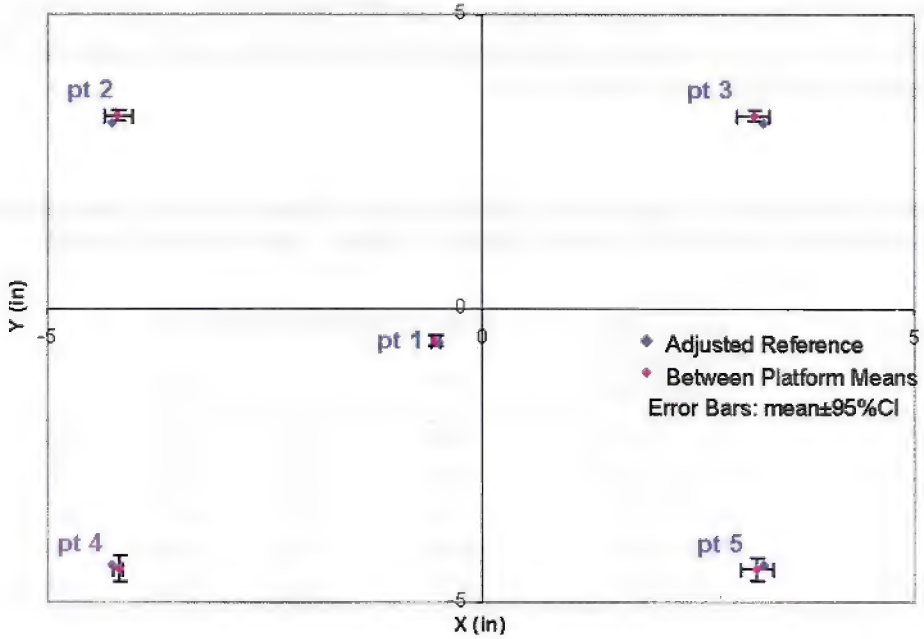


Figure 5. Point Test with adjusted reference points and averaged system by day recordings. Adjusted Reference (darker diamond); Averaged system measurements (lighter diamond); Error bars represent +/- 95%CI



HUMAN TESTING

285 men between 18 and 40 years of age and 284 women between 18 and 41 years of age completed the study. Volunteer demographic statistics are presented in Table 4. One subject requested to terminate her participation in the study prior to any balance measurements being taken. This subject's questionnaire data were not used in any analysis.

Table 4. Participant Demographics.

	Unit of Measurement	Men		Women	
Height Mean (SD)	**cm**	n=279	174.9 (8.3)	n=276	161.9 (8.6)
Weight Mean (SD)	**kg**	n=279	80.9 (13.1)	n=276	64.9 (9.9)
Age Mean (SD)	**yrs**	n=278	22.4 (4.5)	n=278	22.5 (5.2)
Ethnicity (%)	**Caucasian**	n=277	70.4%	n=275	55.3%
	African American		10.1%		21.1%
	Hispanic		13.0%		13.8%
	Asian		1.8%		1.5%
	Latin American		0.4%		0.7%
	Other		4.3%		7.6%
Branch (%)	**Active duty**	n=278	55.0%	n=278	53.2%
	NG		39.6%		33.7%
	Reserve		5.4%		14.0%

97% of the men and 98% of the women completed the questionnaire. Response rates (percentages) of previous injuries are presented in Table 5. The majority of participants (> 90%) denied ever having a head injury, previous sprain or strain, previous loss of consciousness (LOC), or previous ear infection. Over 80% reported that they had never had a broken bone, and over 64% reported never being involved in a motor vehicle accident (MVA). There were no differences between genders in the rates of responses for any of these variables (Mann-Whitney U test; $p > 0.05$). Volunteers were also asked about current medication use. At the time of the testing, 96% of men denied taking any prescription or over the counter (OTC) medications. The 4% of men using OTC and prescription medications, respectively, reported using non-steroidal anti-inflammatory medications (NSAID; 2% OTC, 1.2% prescription), allergy

medication (0.4% OTC, 0.8% prescription), cold medication (0.8% OTC), antibiotics (0.8% prescription), and narcotics (1.2% prescription). 93% and 85% of the women reported not taking any OTC or prescription medications, respectively. Of those taking OTC medications, 4.6% reported taking an NSAID, 1.9% an allergy medication, and 1.2% vitamins. Of those using prescription medications, 6.5% reported using birth control, 4.4% an NSAID, 2.4% allergy medication, 1.2% an antibiotic, and 0.8% a narcotic.

Table 5. History of Previous Injury or Accident. Mann-Whitney U test compared rates of responses between men and women. No differences in response rates were identified ($p > 0.05$).

		N	Never (%)	One Previous (%)	Two Previous (%)	Three Previous (%)	Four Previous (%)	Five Previous (%)
Men	Previous Head Injury	276	90.2	6.2	2.5	0.7	0.4	0
	Previous LOC < 1 min	277	90.3	8.3	1.4	0	0	0
	Previous LOC 1 - 20 min	277	97.5	2.2	0	0.4	0	0
	Previous LOC > 20 min	277	100	0	0	0	0	0
	Previous Motor Vehicle Accident	277	64.3	18.1	9.4	4.7	2.9	0.7
	Previously Broken Bone	276	80.1	13.8	3.3	0.7	0.4	1.8
	Previous Sprain or Strain	276	92.8	5.1	1.1	0.7	0	0.4
	Previous Ear Infection	277	96	1.8	0.7	0.4	0	1.1
Women	Previous Head Injury	278	93.9	4	1.4	0.4	0.4	0
	Previous LOC < 1 min	279	92.1	5.4	2.2	0.4	0	0
	Previous LOC 1 - 20 min	279	96.4	3.2	0.4	0	0	0
	Previous LOC > 20 min	278	99.6	0.4	0	0	0	0
	Previous Motor Vehicle Accident	279	69.2	19.7	3.2	4.3	2.2	1.4
	Previously Broken Bone	278	86	9.4	3.6	0.4	0	0.7
	Previous Sprain or Strain	278	91	6.1	2.5	0.4	0	0
	Previous Ear Infection	279	91.4	5	0.7	0.4	0.4	2.2

Parameters of postural sway recorded by the IsoBalance systems were evaluated for extremes in the range of values. No extreme values were identified that were associated with subjects who reported a previous loss of consciousness, previous head injury, previous MVA, or current use of narcotic or allergy medications. Therefore, data from these subjects were allowed to remain in the model for all analyses.

Analysis of the IsoBalance recordings demonstrated that data were compromised by non-biological randomly generated signaling error of unknown origin (artifact). We observed two categories of artifact during our analysis: Category 1 artifact included single or multiple episodes of signaling error generated during the execution of the test. Category 2 artifact included rampant signaling error occurring after test capture. Category 2 artifact was only observed when the test was reviewed in the Analysis module of the software. Examples of a normal test, category 1 artifact, and category 2 artifact are presented in Figures 6, 7, and 8, respectively.

Figure 6. Normal IsoBalance test for healthy participant standing still with eyes open (BSEO condition). The blue trace in the center of the screen represents the path of the canter of pressure (COP) over a 20-sec trial

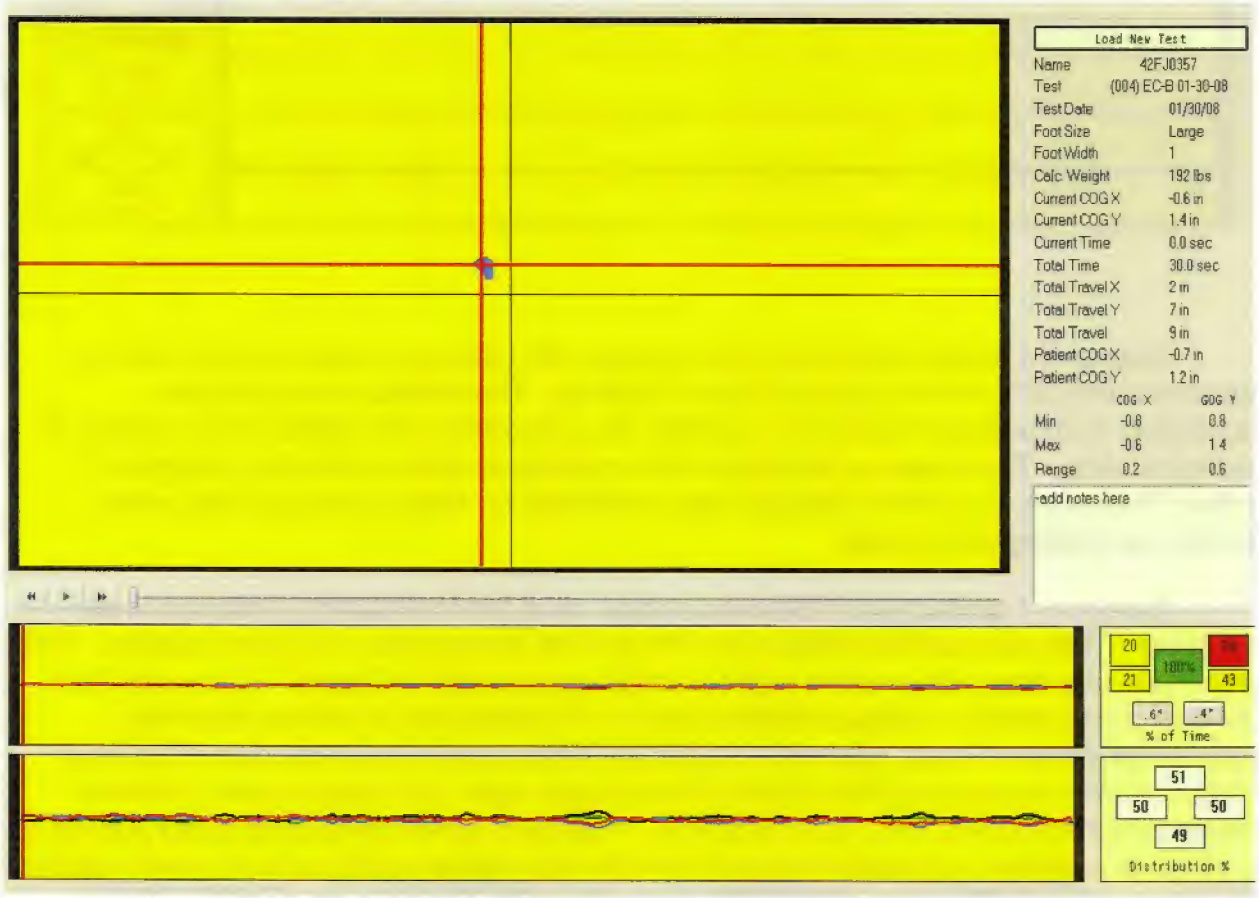
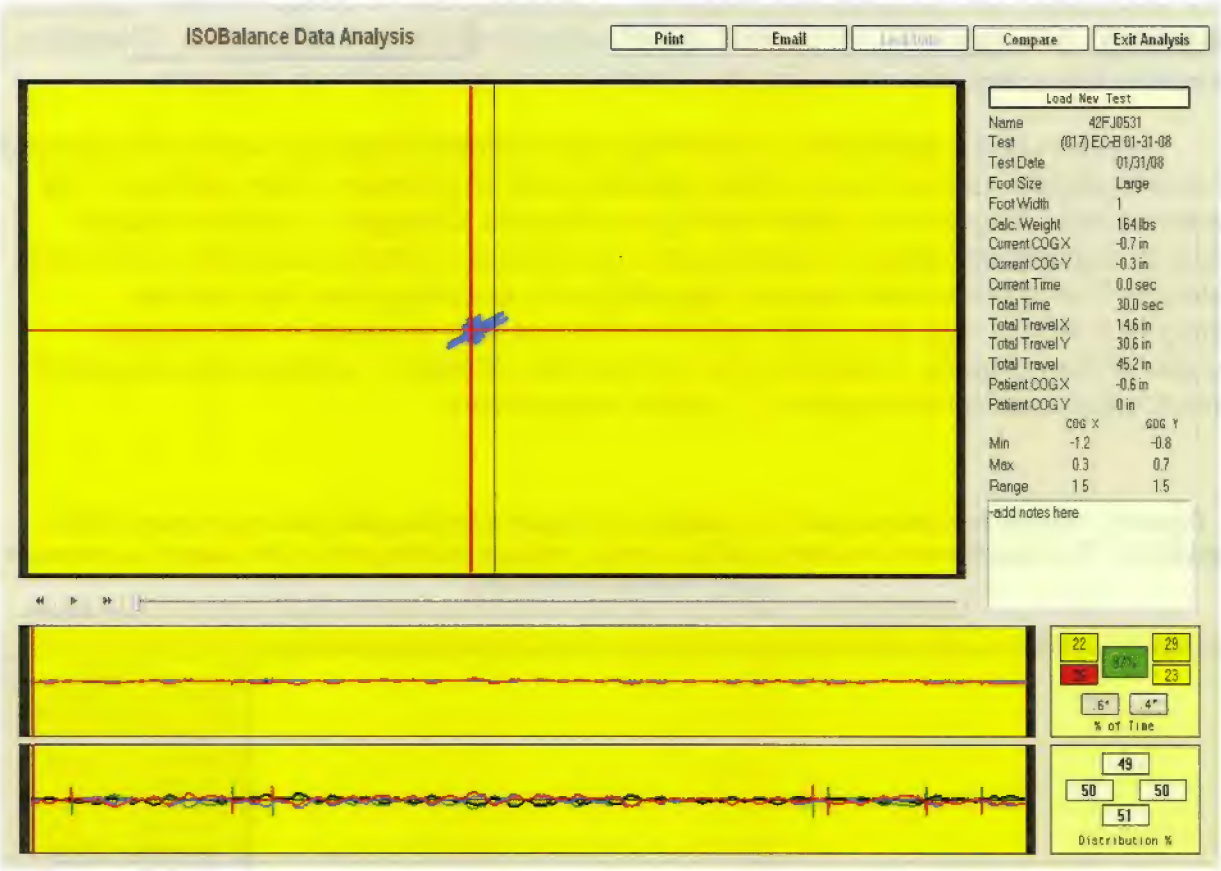


Figure 7. Example of Category 1 artifact. Standard COP measurements are intergrated with non-biological signals of unknown origin during the data collection process

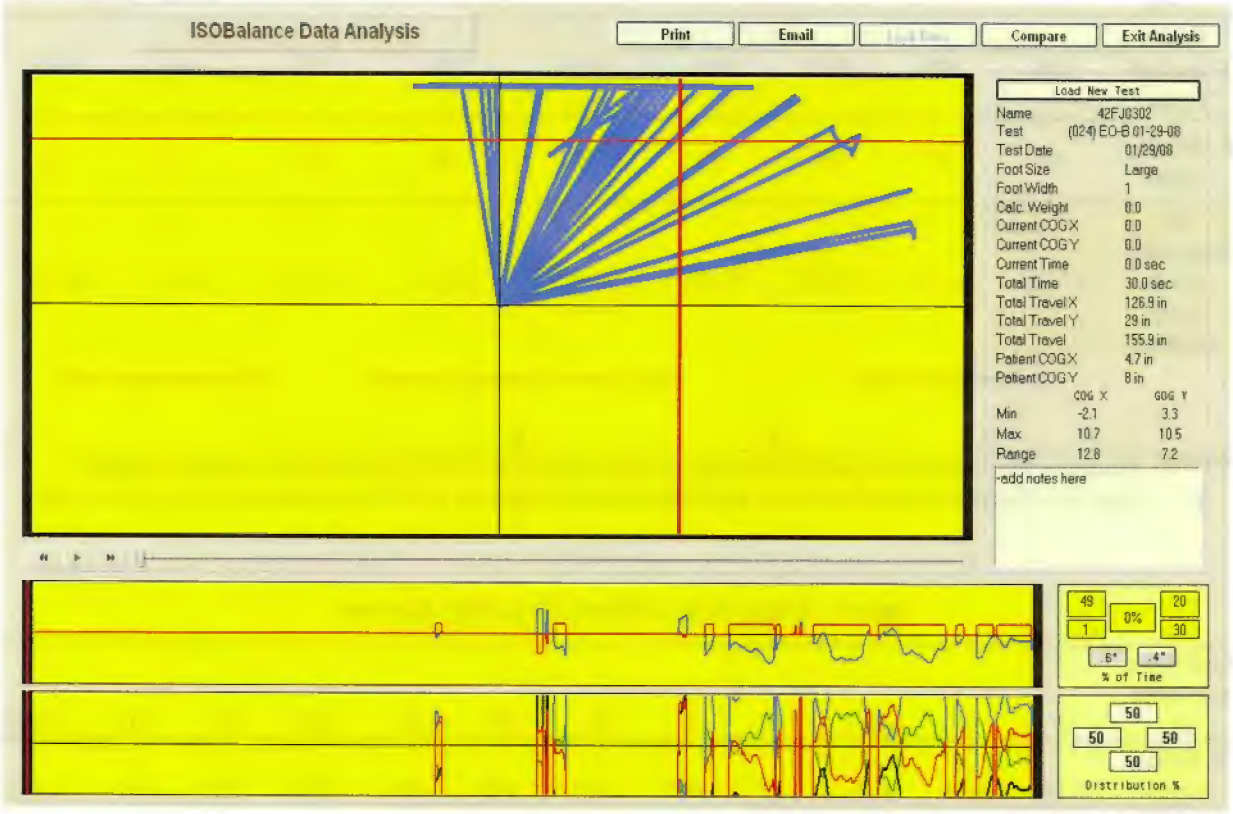


Category 1 artifact occurred concurrently with biological postural sway data in approximately 30% of the recorded trials (Table 6). These data were analyzed separately from artifact free data to quantify the proportion and effects of the artifact on biological data. There was no biological data present in trials containing category 2 artifact; therefore, no further analysis was conducted on these trials and they were treated as missing data points.

Category 1 artifact was observed across all of the IsoBalance platforms in all positions. There was artifact present in 17% to 47% of the trials in a given position. The proportion of artifact observed in each position is presented in Table 7. Separate 95% CI were constructed to compare differences in the proportion of artifact observed between positions. There was not a significant difference in the proportion of artifact observed when comparing the bilateral stance eyes open and eyes closed positions (mean difference 0.4%; 95% CI -5% to 4%). However, when comparing these positions to all other positions, a greater proportion of the less stable positions were contaminated by artifact (mean difference range 5.5% to 30.5%; 95% CI range 1% to 35%). There was a greater proportion of artifact observed during trials of shaking the head compared to nodding (mean difference 5.5%; 95% CI 1% to 10%). Positions of similar stability

challenge (i.e., tandem stance with eyes closed right vs. left foot forward, tandem stance eyes open right vs. left foot forward) demonstrated similar proportions of artifact (mean difference eyes closed 3%; 95% CI -3% to 8% and mean difference eyes open -2.4%; 95% CI -7% to 3%), but there was a greater proportion of artifact present in tandem stance eyes closed trials compared to eyes open trials (mean difference range 15.9% to 21.3%; 95% CI range 11% to 26%).

Figure 8. Example of Category 2 artifact



The proportion of artifact by trial that was observed in each system ranged from 25% to 31% and is presented in Table 7. Separate 95% CI were constructed to compare differences in the proportion of artifact observed between systems. There were no significant differences in the proportion of artifact observed between any of the IsoBalance systems (mean difference range 0.7% to 6.3%; 95% CI range -12% to 9%).

The proportion of system artifact occurring in completed test batteries (at least one of the eight positions contained artifact for a given subject) ranged from 82% to 96% and is presented in Table 8. Confidence interval analysis demonstrated no significant differences in the proportion of completed test batteries contaminated by artifact between any of the IsoBalance systems (mean difference range 3% to 13.9%; 95% CI range -29% to 18%).

Table 6. Trials With Artifact, Listed By Test Position.

Test Position	BSEO	BSEC	NOD	SHAKE	TSLREO	TSRLEO	TSLREC	TSRLEC	Total
# Trials with Artifact	107	105	141	175	161	177	284	273	1423
Total Recorded Trials	625	627	625	622	622	626	602	617	4966
Total Expected Trials	636	636	636	636	636	636	636	636	5088
# Missing Trials	11	9	11	14	14	10	34	19	122
% Recorded Trials with Artifact	17.1%	16.7%	22.6%	28.1%	25.9%	28.3%	47.2%	44.2%	28.7%

Denotes all proportions are statistically similar based on 95% confidence interval analysis.

Denotes discrete proportions are statistically similar based on 95% confidence interval analysis.

Table 7. Trials With Artifact, Listed By System.

IsoBalance System #	1	3	4	5	6	8	9	14	15	16	17	Total
# Trials with Artifact	113	130	103	122	147	144	147	67	230	153	67	1423
Total Recorded Trials	454	507	391	396	519	461	503	228	768	507	232	4966
Total Attempted Trials	480	512	424	400	520	464	512	240	776	512	232	5072
# Trials Missing Data	26	5	33	4	1	3	9	12	8	5	0	106
% Recorded Trials with Artifact	24.9 %	25.6 %	26.3 %	30.8 %	28.3 %	31.2 %	29.2 %	29.4 %	29.9 %	30.2 %	28.9 %	28.7 %

Proportions of artifact between all systems were similar based on 95% confidence interval analysis (all 95% CI contained a 0 value).

Table 8. Trials With Artifact, Listed By Test Battery.

IsoBalance System #	1	3	4	5	6	8	9	14	15	16	17	Total
# Batteries with Artifact	44	52	39	43	58	52	50	22	79	56	27	523
Total Recorded Batteries	55	60	46	47	64	55	56	23	89	59	29	583
Total Attempted Batteries	60	64	53	50	65	58	64	30	97	64	29	634
# Incomplete Batteries	5	4	7	3	1	3	8	7	8	5	0	51
% Recorded Batteries with Artifact	81.8 %	86.7 %	84.8 %	91.5 %	90.6 %	94.5 %	89.3 %	95.7 %	88.8 %	94.9 %	93.1 %	89.7 %

Test Battery = All 8 Test Positions Completed. Proportions of artifact between completed test batteries on all systems were similar based on 95% confidence interval analysis (all 95% CI contained a 0 value).

The artifact artificially decreased the percentage of time that the COP was maintained in an area of 0.2 in, 0.4 in, and 0.6 in of the mean COP for the trial and artificially increased COP displacement and excursion measurements (Tables 9 through 16).

Table 9. Bilateral Stance Eyes Open (Rhomberg Test).

BSEO: Completed Trials with Artifact (N = 105)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	71.93 (20.30)	93.59 (12.36)	98.29 (6.23)	9.05 (4.46)	1.08 (0.57)	1.25 (0.74)	3.78 (2.21)	5.27 (2.41)
95% CI	68.01 - 75.86	91.20 - 95.98	97.08 - 99.49	8.18 - 9.91	0.97 - 1.19	1.11 - 1.40	3.35 - 4.20	4.81 - 5.74
Range	0 - 99	0 - 100	38 - 100	2 - 25.2	0 -5.3	0 - 7.8	0 – 11.3	1.6 - 13.9
CV	28.2	13.2	6.3	49.3	52.5	59.5	58.6	45.8

BSEO: Completed Trials without Artifact (N = 516)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	79.98 (15.67)	97.07 (6.17)	99.47 (2.15)	3.00 (1.93)	0.22 (0.17)	0.51 (0.26)	0.81 (0.90)	2.18 (1.32)
95% CI	78.60 - 81.36	96.53 - 97.62	99.28 - 99.66	2.83 - 3.17	0.20 - 0.23	0.49 - 0.53	0.73 - 0.89	2.07 - 2.30
Range	22 - 100	36 - 100	70 - 100	0 - 12.5	0 - 1.2	0 - 2.2	0 - 6.2	0 - 9
CV	19.6	6.4	2.2	64.6	77.6	51.4	110.9	60.3

BSEO: Completed Test Batteries without Artifact (N = 60)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	80.17 (15.03)	97.12 (6.18)	99.42 (1.83)	2.92 (2.11)	0.21 (0.16)	0.50 (0.28)	0.81 (0.89)	2.11 (1.44)
95% CI	76.29 - 84.05	95.52 - 98.71	98.94 - 99.89	2.37 - 3.47	0.17 - 0.25	0.43 - 0.57	0.58 - 1.04	1.74 - 2.48
Range	41 - 100	64 - 100	89 - 100	0.4 - 9.4	0 - 1	0 - 1.4	0 - 3.4	0 - 6.2
CV	18.7	6.4	1.8	72.3	75.0	55.4	109.8	68.1

Table 10. Bilateral Stance Eyes Closed (Rhomberg Test).

BSEC: Completed Trials with and without Artifact (N = 102)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	59.53 (21.85)	85.75 (17.17)	94.79 (11.74)	14.67 (17.13)	1.21 (0.60)	1.36 (0.42)	5.60 (8.77)	9.06 (8.83)
95% CI	55.24 - 63.82	82.38 - 89.13	92.49 - 97.10	11.30 - 18.03	1.09 - 1.33	1.27 - 1.44	3.88 - 7.33	7.33 - 10.80
Range	0 - 97	0 - 100	0 - 100	1.1 - 171	0.2 - 4	0 - 3	0.6 - 80	0 - 91
CV	36.7	20.0	12.4	116.8	49.9	31.1	156.4	97.5

BSEC: Completed Test Batteries without Artifact (N = 522)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	66.87 (18.53)	91.65 (10.69)	97.84 (4.81)	6.58 (3.47)	0.33 (0.21)	0.81 (0.34)	1.57 (1.58)	5.01 (2.42)
95% CI	65.25 - 68.49	90.71 - 92.58	97.42 - 98.27	6.27 - 6.88	0.32 - 0.35	0.78 - 0.84	1.43 - 1.71	4.80 - 5.22
Range	8 - 99	30 - 100	53 - 100	0.4 - 31.6	0 - 1.3	0 - 2.4	0 - 16.7	0 - 14.9
CV	27.7	11.7	4.9	52.7	61.5	42.6	100.5	48.4

BSEC: Completed Test Batteries without Artifact (N = 60)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	73.03 (17.39)	94.22 (8.90)	98.73 (2.99)	5.91 (3.56)	0.30 (0.20)	0.74 (0.32)	1.38 (1.32)	4.53 (2.53)
95% CI	68.54 - 77.52	91.92 - 96.51	97.96 - 99.50	4.99 - 6.83	0.25 - 0.35	0.65 - 0.82	1.04 - 1.72	3.87 - 5.18
Range	26 - 98	61 - 100	83 - 100	0.4 - 21.8	0 - 0.8	0 - 1.8	0 - 7	0 - 14.8
CV	23.8	9.4	3.0	60.3	67.4	43.9	95.6	55.8

Table 11. Bilateral Stance Nodding Head.

BSNOD: Completed Trials with and without Artifact (N = 138)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	52.16 (19.66)	82.74 (16.75)	93.20 (12.30)	20.45 (24.80)	1.23 (0.55)	1.44 (0.63)	8.67 (12.17)	11.78 (13.74)
95% CI	48.85 - 55.47	79.92 - 85.56	92.49 - 97.10	16.27 - 24.62	1.14 - 1.32	1.34 – 1.55	6.62 - 10.72	9.46 - 14.09
Range	0 - 98	17 - 100	18 - 100	5.4 - 288	0 - 5	0 - 6	0 - 132	0 - 156
CV	37.7	20.3	13.2	121.3	44.8	43.3	140.3	116.7

BSNOD: Completed Trials without Artifact (N = 483)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	60.56 (18.43)	88.66 (12.68)	96.71 (6.70)	10.05 (6.62)	0.47 (0.31)	0.86 (0.38)	3.63 (3.41)	6.42 (4.11)
95% CI	58.88 - 62.24	87.51 - 89.82	96.10 - 97.32	9.45 - 10.66	0.45 - 0.50	0.83 - 0.90	3.32 - 3.94	6.05 - 6.80
Range	6 - 96	15 - 100	36 - 100	1.2 - 58.4	0 – 2.8	0.2 - 3.3	0 - 31.8	0.4 - 28.5
CV	30.4	14.3	6.9	65.8	66.0	44.3	93.9	64.0

BSNOD: Completed Test Batteries without Artifact (N = 60)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	62.90 (18.25)	90.42 (11.10)	97.73 (5.10)	9.75 (6.52)	0.45 (0.28)	0.83 (0.37)	3.31 (2.51)	6.44 (4.97)
95% CI	58.19 - 67.61	87.55 - 93.28	96.42 - 99.05	8.06 - 11.43	0.38 - 0.52	0.73 - 0.92	2.66 - 3.95	5.15 - 7.72
Range	14 - 95	39 - 100	67 - 100	1.2 - 34.2	0 - 1.6	0.2 - 2	0 - 13.6	0.8 - 28.5
CV	29.0	12.3	5.2	66.9	61.6	44.3	75.9	77.2

Table 12. Bilateral Stance Shaking Head.

BSSHAKE: Completed Trials with and without Artifact (N = 177)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	50.24 (18.58)	81.50 (15.65)	93.37 (10.21)	20.47 (9.52)	1.18 (0.51)	1.49 (0.67)	6.30 (3.44)	14.17 (7.27)
95% CI	47.49 - 53.00	79.18 - 83.82	91.85 - 94.88	19.06 - 21.88	1.10 - 1.26	1.40 - 1.59	5.79 - 6.81	13.09 - 15.25
Range	0 - 94	0 - 100	0 - 100	0.6 - 52.2	0.2 - 5.9	0 - 8.5	0 - 16.2	0 - 37.6
CV	37.0	19.2	10.9	46.5	43.6	44.7	54.5	51.3

BSSHAKE: Completed Trials without Artifact (N = 443)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	60.41 (19.07)	88.12 (13.28)	96.37 (7.05)	11.62 (8.32)	0.40 (0.33)	0.93 (0.44)	2.65 (2.65)	8.97 (6.63)
95% CI	58.60 - 62.23	86.86 - 89.38	95.70 - 97.04	10.83 - 12.41	0.37 - 0.44	0.89 - 0.97	2.40 - 2.90	8.34 - 9.60
Range	6 - 99	35 - 100	51 - 100	0.8 - 62.5	0 - 4.5	0.2 - 3	0 - 21.4	0.4 - 55.5
CV	31.6	15.1	7.3	71.6	82.0	47.2	100.0	73.9

BSSHAKE: Completed Test Batteries without Artifact (N = 60)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	62.50 (19.95)	88.32 (14.09)	96.45 (6.38)	10.90 (8.03)	0.40 (0.25)	0.86 (0.45)	2.64 (2.53)	8.26 (6.54)
95% CI	57.35 - 67.65	84.68 - 91.95	94.80 - 98.10	8.83 - 12.97	0.34 - 0.47	0.74 - 0.98	1.99 - 3.29	6.57 - 9.95
Range	19 - 99	41 - 100	71 - 100	2 - 51.7	0 - 1.2	0.2 - 2.9	0 - 14.2	1.2 - 44.7
CV	31.9	15.9	6.6	73.7	62.3	52.7	95.7	79.1

Table 13. Tandem Stance Left Foot Forward Eyes Open (Sharpened Rhomberg Test).

TSLREO: Completed Trials with and without Artifact (N = 159)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	40.66 (20.93)	72.27 (22.04)	86.53 (17.26)	23.55 (11.33)	1.33 (0.47)	1.57 (0.88)	12.61 (5.45)	10.94 (6.70)
95% CI	37.38 - 43.94	68.82 - 75.72	83.82 - 89.23	21.78 - 25.33	1.26 - 1.40	1.43 - 1.71	11.76 - 13.47	9.89 - 11.99
Range	0 - 95	0 - 100	2 - 100	8.2 - 88.6	0.7 - 4.3	0 - 7.1	1.6 - 44	1.5 - 45
CV	51.5	30.5	20.0	48.1	35.3	55.9	43.2	61.3

TSLREO: Completed Trials without Artifact (N = 461)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	45.44 (20.55)	77.00 (20.45)	89.94 (14.92)	16.02 (8.71)	0.79 (0.64)	1.22 (0.86)	8.46 (4.47)	7.56 (4.91)
95% CI	43.53 - 47.36	75.09 - 78.90	88.55 - 91.33	15.21 - 16.83	0.74 - 0.85	1.14 - 1.30	8.05 - 8.88	7.10 - 8.01
Range	0 - 100	2 - 100	2 - 100	0 - 88.8	0 – 11.9	0 - 8.6	0 - 48.2	0 - 41.5
CV	45.2	26.6	16.6	54.4	80.1	70.9	52.8	65.0

TSLREO: Completed Test Batteries without Artifact (N = 60)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	48.17 (20.97)	78.68 (20.21)	90.22 (15.91)	15.01 (6.95)	0.72 (0.27)	1.23 (0.93)	7.52 (2.92)	7.49 (4.70)
95% CI	42.75 - 53.58	73.46 - 83.90	86.11 - 94.32	13.22 - 16.80	0.65 - 0.79	0.99 - 1.47	6.77 - 8.28	6.27 - 8.70
Range	0 - 87	2 - 99	2 - 100	5 - 35.5	0.2 - 1.6	0.4 - 5.1	0.6 - 16.2	2.4 - 19.3
CV	43.5	25.7	17.6	46.3	37.2	75.7	38.9	62.8

Table 14. Tandem Stance Left Foot Forward Eyes Closed (Sharpened Rhomberg Test).

TSLREC: Completed Trials with and without Artifact (N = 278)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	14.55 (10.26)	35.90 (18.68)	55.63 (22.42)	60.05 (27.05)	2.52 (1.79)	3.18 (2.49)	32.77 (12.32)	27.28 (16.43)
95% CI	13.34 - 15.76	33.69 - 38.10	52.98 - 58.28	56.86 - 63.24	2.31 - 2.73	2.88 - 3.47	31.32 - 34.22	25.34 - 29.22
Range	0 -52	0 - 82	0 - 96	20 - 160	1 - 15.4	0 -13.9	12 - 76	1 - 108
CV	70.5	52.0	40.3	45.0	71.0	78.2	37.6	60.2

TSLREC: Completed Trials without Artifact (N = 317)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	19.13 (14.26)	43.65 (21.16)	63.96 (22.45)	46.97 (22.45)	2.02 (1.43)	2.52 (1.96)	26.01 (10.76)	20.96 (13.49)
95% CI	17.53 - 20.73	41.23 - 46.03	61.44 - 66.48	44.45 - 49.50	1.86 - 2.18	2.30 - 2.74	24.80 - 27.22	19.45 - 22.48
Range	0 – 99	0 - 100	0 - 100	0 - 142.4	0 – 16.7	0 -12.2	0 - 74.8	0 - 78.2
CV	74.6	48.5	35.1	47.8	70.5	78.0	41.4	64.4

TSLREC: Completed Test Batteries without Artifact (N = 59)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	22.75 (17.40)	48.24 (22.76)	67.75 (21.91)	44.17 (21.32)	2.00 (1.46)	2.57 (2.16)	23.97 (9.45)	20.19 (13.14)
95% CI	18.22 - 27.28	42.31 - 54.16	62.04 - 73.45	38.62 - 49.72	1.62 - 2.38	2.01 - 3.14	21.51 - 26.43	16.77 - 23.62
Range	0 – 99	0 - 100	6 - 100	1.2 - 105.7	0 - 11.3	0.2 - 10.9	0 - 57.3	1.2 - 63.7
CV	76.5	47.2	32.3	48.3	72.9	83.8	39.4	65.1

Table 15. Tandem Stance Right Foot Forward Eyes Open (Sharpened Rhomberg Test).

TSRLEO: Completed Trials with and without Artifact (N = 172)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	46.33 (21.48)	78.26 (19.74)	91.09 (12.50)	20.90 (10.20)	1.27 (0.36)	1.30 (0.64)	11.37 (5.30)	9.53 (5.52)
95% CI	43.09 - 49.56	75.29 - 81.23	89.21 - 92.97	19.36 - 22.44	1.21 - 1.32	1.21 - 1.40	10.57 - 12.17	8.70 - 10.36
Range	1 - 92	13 - 99	38 - 100	7.6 - 65.5	0.4 - 2.5	0.4 - 6	4 - 37	2 – 30
CV	46.4	25.2	13.7	48.8	28.2	49.4	46.6	57.9

TSRLEO: Completed Trials without Artifact (N = 449)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	50.23 (21.02)	81.26 (19.92)	92.67 (13.85)	14.23 (8.00)	0.77 (0.73)	1.07 (1.11)	7.67 (3.69)	6.56 (4.97)
95% CI	48.24 - 52.21	79.38 - 83.14	91.36 - 93.98	13.48 - 14.99	0.70 - 0.84	0.97 - 1.18	7.32 - 8.02	6.09 - 7.03
Range	0 - 100	0 - 100	0 - 100	0 - 90.9	0 – 11	0 - 14.2	0 - 32.1	0 – 65.5
CV	41.8	24.5	14.9	56.2	95.2	103.0	48.0	75.7

TSRLEO: Completed Test Batteries without Artifact (N = 60)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	52.18 (20.84)	82.80 (18.25)	92.77 (12.76)	13.17 (7.47)	0.84 (0.95)	1.03 (0.78)	7.02 (3.58)	6.15 (4.34)
95% CI	46.80 - 57.56	78.09 - 87.51	89.47 - 96.06	11.24 - 15.10	0.60 - 1.09	0.83 - 1.23	6.09 - 7.94	5.03 - 7.27
Range	8 - 90	21 - 100	38 - 100	4.8 - 47.8	0.4 - 7.4	0.2 - 4.1	2.2 - 24.7	1 – 23.1
CV	39.9	22.0	13.7	56.7	113.0	75.2	51.0	70.6

Table 16. Tandem Stance Right Foot Forward Eyes Closed (Sharpened Rhomberg Test).

TSRLEC: Completed Trials with and without Artifact (N = 271)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	13.72 (10.40)	35.39 (19.25)	55.44 (22.92)	62.30 (29.78)	2.86 (2.39)	3.24 (2.64)	33.81 (13.71)	28.49 (18.89)
95% CI	12.47 - 14.96	33.09 - 37.70	52.70 - 58.18	58.74 - 65.86	2.57 - 3.15	2.93 - 3.56	32.17 - 35.45	26.23 - 30.75
Range	0 – 81	0 - 97	0 - 100	13 - 201	0.9 - 14.5	0.6 - 16.6	8 - 127	5 – 144
CV	75.8	54.4	41.3	47.8	83.6	81.3	40.6	66.3

TSRLEC: Completed Trials without Artifact (N = 344)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	18.58 (13.95)	43.04 (20.96)	63.29 (21.88)	49.13 (25.08)	2.09 (1.29)	2.51 (1.82)	27.01 (11.11)	22.12 (15.75)
95% CI	17.07 - 20.08	40.78 - 45.30	60.93 - 65.65	46.43 - 51.84	1.95 - 2.23	2.32 - 2.71	25.81 - 28.21	20.42 - 23.82
Range	0 – 99	0 - 100	0 - 100	1 - 218.2	0 - 11.8	0 - 12.2	0 - 73.9	0 - 144.3
CV	75.1	48.7	34.6	51.1	61.9	72.6	41.1	71.2

TSRLEC: Completed Test Batteries without Artifact (N = 60)*

	.2 inch circle (% time)	.4 inch circle (% time)	.6 inch circle (% time)	Total Travel (in)	Dif_X (in)	Dif_Y (in)	Total Travel X (in)	Total Travel Y (in)
Mean (SD)	22.28 (16.56)	48.77 (22.00)	68.30 (21.21)	45.31 (24.12)	2.12 (1.60)	2.28 (1.60)	25.06 (10.01)	20.25 (15.64)
95% CI	18.01 - 26.56	43.09 - 54.45	62.82 - 73.78	39.08 - 51.54	1.71 - 2.53	1.86 - 2.69	22.48 - 27.65	16.21 - 24.29
Range	0 - 99	3 - 100	8 - 100	1.8 - 141.7	0.2 - 9.7	0.2 - 7.4	0.2 - 54.8	1.6 - 86.9
CV	74.3	45.1	31.1	53.2	75.3	70.4	39.9	77.2

Separate independent samples t-tests were performed to compare trials with artifact to trials without artifact for each position for each variable of interest. Mean difference scores with their associated 95% confidence intervals for each variable of interest across each position are presented in Figures 9 through 16.

The percent of time that the COP was maintained in an area of 0.2 in of the mean COP for the trial demonstrated an average decrease between 4% and 10% depending on position in trials with artifact compared to those without (Figure 9), these differences were statistically significant for each position ($p < 0.05$). The percentage of time that the COP was maintained in an area of 0.4 in of the mean COP for the trial was decreased on average between 3% and 8% depending on position in trials with artifact compared to those without (Figure 10). These differences were statistically significant for each position ($p < 0.05$), except terminal stance with the left foot forward and eyes open (TSLREO), where no difference between trials with and without artifact was found. The percentage of time that the COP was maintained in an area of 0.6 in of the mean COP for the trial was decreased on average between 1% and 8% depending on position in trials with artifact compared to those without (Fig 11). These differences were statistically significant for each position ($p < 0.05$), except bilateral stance with eyes open (BSEO) and TSLREO, where no difference was found between trials with and without artifact.

Total COP excursion (travel) increased between 6 and 13 inches on average in trials with artifact compared to those without (Figure 12; $p < 0.05$ all positions), and the mean increase in peak to peak A/P COP displacement ranged between 0.5 inches and 0.87 inches in trials with artifact compared to those without (Figure 13; $p < 0.05$ all positions). Peak to peak M/L COP displacement increased on average between 0.25 inches and 0.75 inches in trials with artifact compared to those without (Figure 14; $p < 0.05$ all positions). The mean increase in total A/P COP excursion (travel) ranged between 3 and 7 inches depending on test position (Figure 15; $p < 0.05$ all positions). Total M/L COP excursion (travel) increased on average between 3 and 6 inches depending on test position (Figure 16; $p < 0.05$ all positions).

Figure 9. COP maintenance in 0.2 inch area around the mean COP: Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95%CI; " * " represents statistically significant difference between means (p < 0.05).

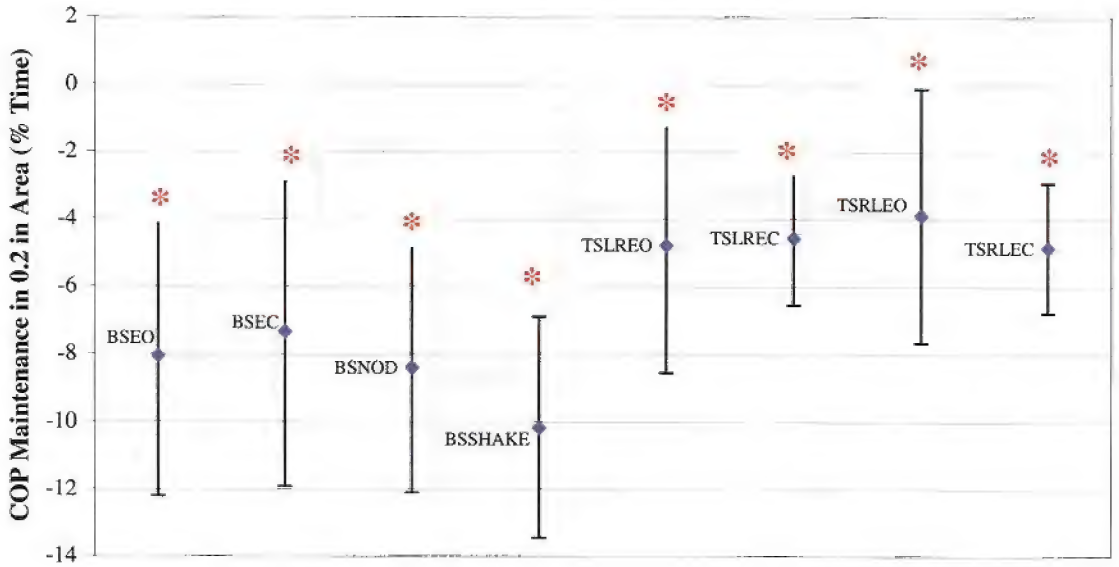


Figure 10. COP maintenance in 0.4 inch area around the mean COP: Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95%CI; " * " represents statistically significant difference between means (p < 0.05).

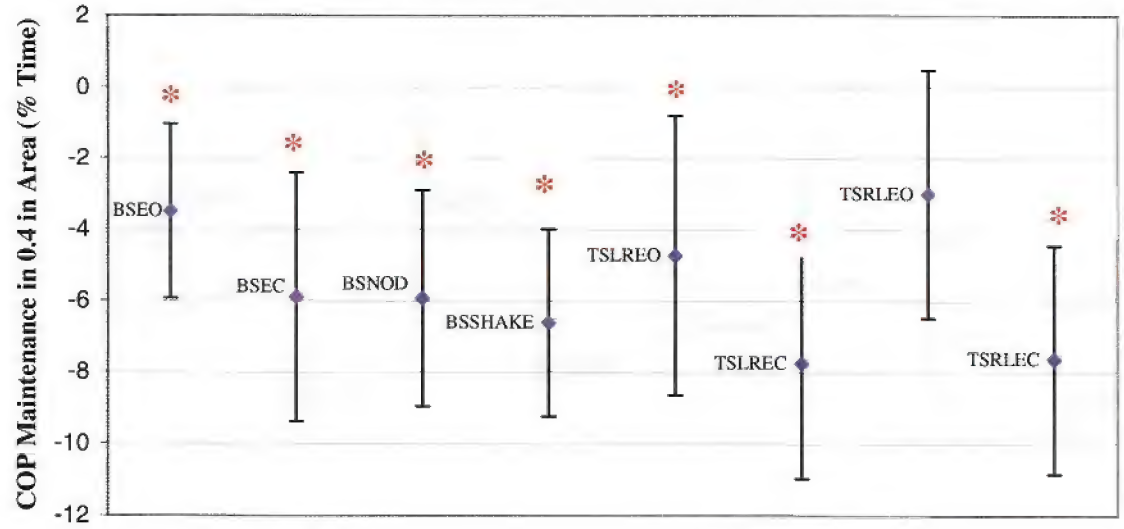


Figure 11. COP maintenance in 0.6 inch area around the mean COP: Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95% CI; " * " represents statistically significant difference between means (p < 0.05)

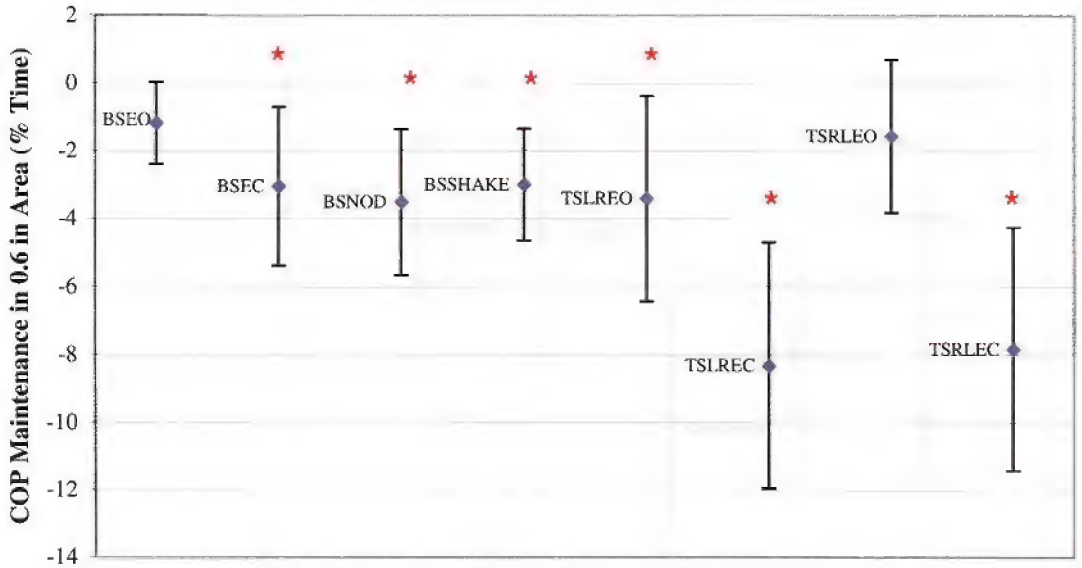


Figure 12. Total COP excursion: Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95%CI; " * " denotes statistically significant difference between means (p < 0.05)

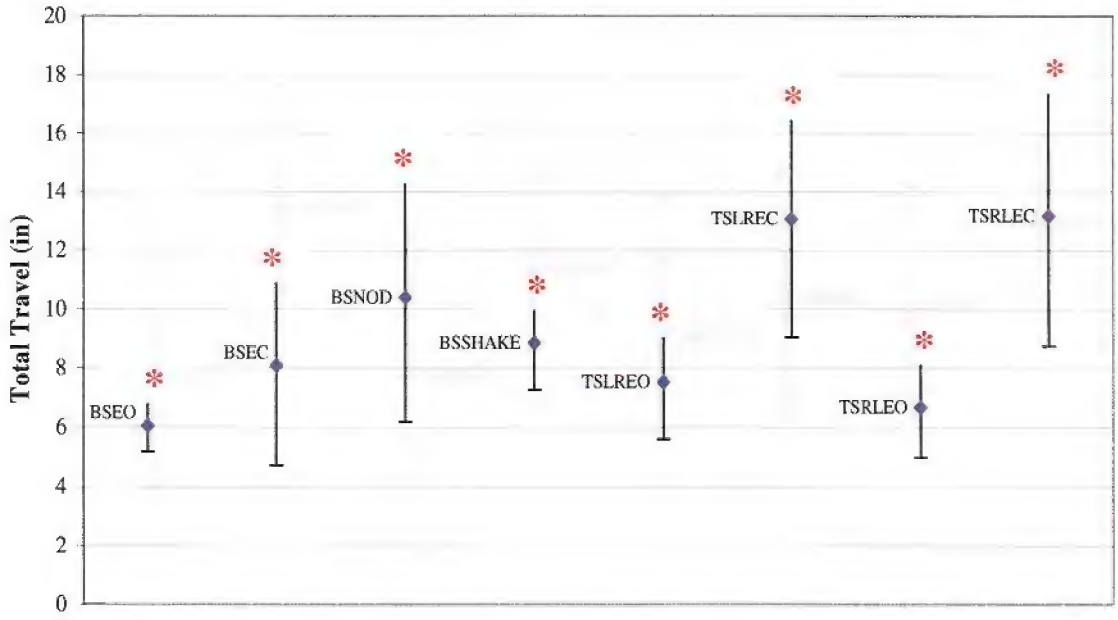


Figure 13. Peak to peak A/P COP displacement (in): Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95%CI; " * " denotes statistically significant difference between means (p < 0.05).

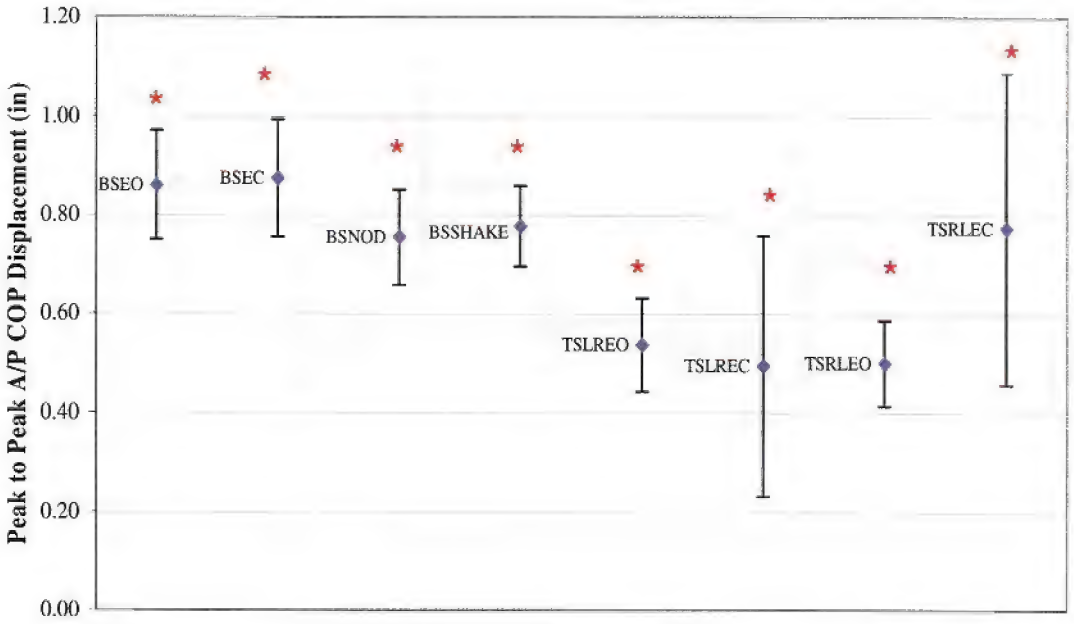


Figure 14. Peak to peak M/L COP displacement (in): Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95%CI; " * " denotes statistically significant difference between means (p < 0.05).

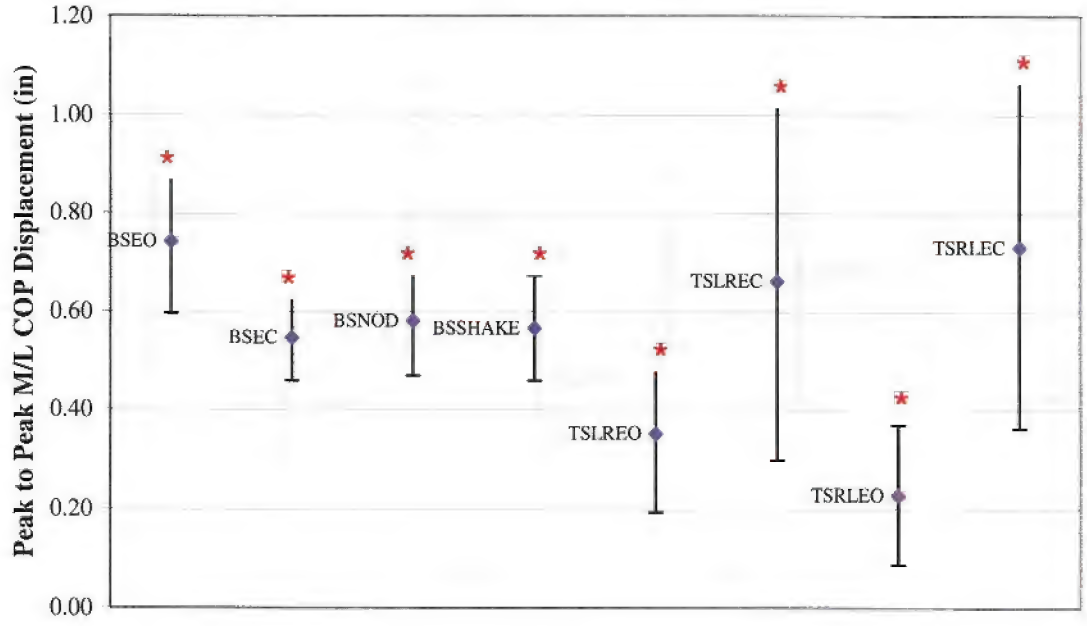


Figure 15. Total A/P COP excursion (in): Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95%CI; " * " denotes statistically significant difference between means (p < 0.05).

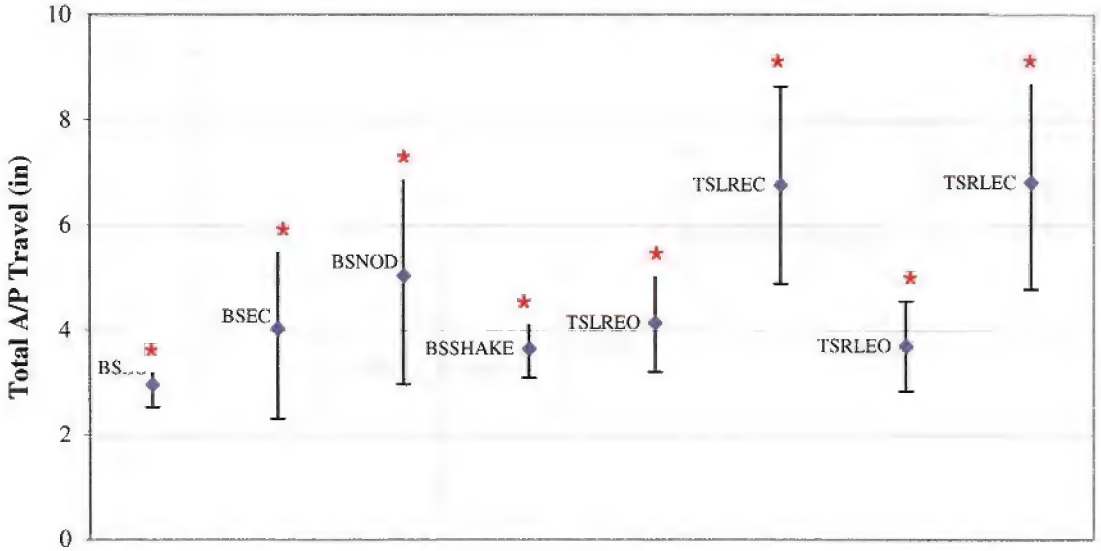
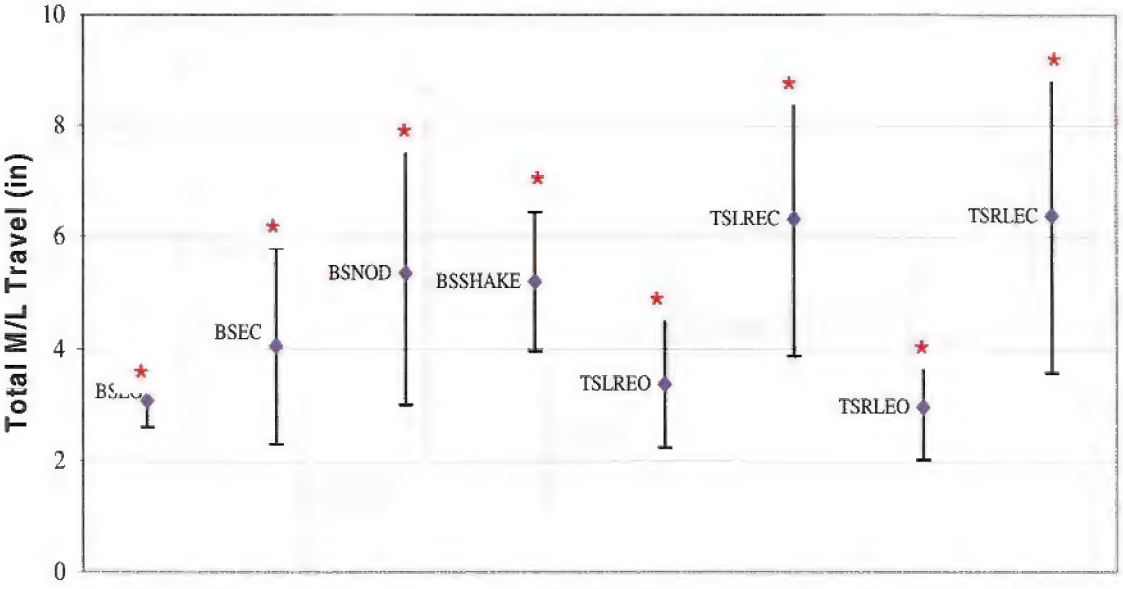


Figure 16. Total M/L COP excursion (in): Comparison of trials with and without artifact. Diamonds represent mean difference between artifact classification; error bars represent 95%CI; " * " denotes statistically significant difference between means (p < 0.05).



Intraclass correlation coefficients (ICC 3,1) were calculated to determine the test-retest reliability associated with each IsoBalance variable of interest (Table 17). Several classifications of reliability exist but, in general, they agree that ICC estimates below 0.33 are poor. Those between 0.33 and 0.75 are fair, those over 0.75 are good, and those > 0.90 are excellent (5, (16, (20). It is widely accepted that reliability of tests used for clinical purposes should exceed 0.90. Overall, the reliability of the IsoBalance was poor. Forty-four percent of the variables of interest failed to reach statistical significance on repeated testing, owing to the large variability between measurements within a particular individual. Of those variables that reached statistical significance (39/64), 74% demonstrated only fair reliability (ICC < 0.75). Only 10 variables demonstrated good reliability, and of these, only 1 was acceptable for clinical test standards (> 0.90).

Coefficients of variation (% CV) were calculated for repeated trials to identify the proportional magnitude of error associated with each variable of interest for each position (Table 18). These estimates varied widely, but were generally high (52 of 64 estimates were > 20%).

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Table 17. Intraclass Correlation Coefficients (ICC 3,1) Based on 3 Repeated Trials. NS denotes ICC failed to reach statistical significance. Good reliability = ICC > 0.75. Acceptable clinical reliability = ICC ≥ 0.9.

Variable	BSEO (n=15)	NOD (n=8)	BSEC (n=15)	SHAKE (n=8)	LREO (n=12)	LREC (n=6)	RLEO (n=16)	RLEC (n=12)
Total travel (in)	0.39	0.67	0.78	0.84	0.55	NS	0.71	0.66
.2 in Circle (% time)	NS	0.69	0.44	0.70	NS	NS	0.42	0.54
.4 in Circle (% time)	NS	0.58	0.43	0.81	NS	NS	NS	0.65
.6 in Circle (% time)	NS	0.58	0.58	0.85	NS	NS	NS	0.72
Dif x (in)	NS	NS	NS	0.68	NS	NS	0.61	NS
Dif y (in)	NS	0.76	0.76	0.64	0.43	NS	NS	0.37
Tot Travel x (in)	0.41	0.75	0.35	0.46	NS	NS	0.73	0.78
Tot Travel y (in)	NS	0.59	0.79	0.91	0.59	NS	0.65	0.57

Table 18. Mean Coefficients of Variation Based on 3 Repeated Trials.

Variable	BSEO (n=15)	NOD (n=8)	BSEC (n=15)	SHAKE (n=8)	LREO (n=12)	LREC (n=6)	RLEO (n=16)	RLEC (n=12)
Total travel (in)	65.9	45.6	43.2	52.2	39.9	43.3	34.8	56.2
.2 in Circle (% time)	20.6	38.8	28.5	29.0	39.3	51.3	46.1	74.7
.4 in Circle (% time)	6.0	20.0	13.8	13.5	19.5	34.7	28.2	56.7
.6 in Circle (% time)	1.5	9.5	6.5	6.0	7.1	23.2	16.9	44.2
Dif x (in)	80.1	45.6	54.3	53.0	29.6	49.0	38.1	51.9
Dif y (in)	46.2	41.3	42.1	33.9	46.6	82.1	54.8	52.5
Tot Travel x (in)	109.0	60.3	68.4	67.2	30.9	30.9	30.0	42.3
Tot Travel y (in)	58.7	45.7	43.6	50.7	59.5	63.5	51.4	74.1

Linear regression equations demonstrated little relationship between the percentage of time the subject's COP was maintained within an area 0.6 inches in diameter of the subject's mean COP (.6 in circle) and any measurement of COP displacement or excursion. Coefficients of determination (r^2) were evaluated from these equations and are reported in Table 19. The coefficient of determination measures the ability of one variable to explain the variability in a second variable. In other words, it is a measurement of the sensitivity a variable has to predict changes in another variable. When subjects assumed a position of bilateral stance with the eyes open, only 1/125 to 1/3 of the variability in the .6 in circle could be explained by either displacement or excursion measurements, indicating that the .6 in circle lacks sensitivity in estimating postural sway in this position. Coefficients of determination improved slightly between variables of interest in other positions. However, the .6 in circle failed to ever explain more that half of the variability of COP excursion. It performed adequately in predicting changes in frontal plane (medial / lateral) displacement, consistently explaining over 50% of the variance in these measurements across six of eight positions, but failed to adequately explain variance in sagittal plane (anterior / posterior) displacement in any position.

Table 19. Regression Coefficients (r^2) of .6 in Circle Compared to Excursion and Displacement Measurements. Blank cells (--) indicate no correlation between variables.

Excursion/ Displacement Measurement	BSEO (n=516)	BSEC (n=522)	NOD (n=483)	SHAKE (n=443)	LREO (n=461)	LREC (n=317)	RLEO (n=449)	RLEC (n=344)
Total Travel	0.12	0.26	0.49	0.43	0.31	0.35	0.37	0.43
A/P Travel	0.04	0.15	0.38	0.29	0.14	0.26	0.14	0.36
M/L Travel	0.13	0.23	0.37	0.37	0.31	0.34	0.36	0.39
Total Displacement	0.34	0.56	0.69	0.71	--	--	0.6	0.54
A/P Displacement	0.14	0.16	0.46	0.4	0.13	0.13	0.17	0.28
M/L Displacement	0.32	0.55	0.6	0.64	0.61	0.4	0.58	0.53

DISCUSSION

The purpose of this report was to assess the potential utility of the IsoBalance in measuring balance in Soldiers to establish baseline measurements of balance, with the intention of using this device as a screening tool to detect difference between individuals with and without mTBI. The IsoBalance performed poorly in the laboratory and in a controlled field environment, with problems ranging from mechanical difficulty to poor resolution of clean data. Mechanical difficulties included failure to operate, and approximately 90% of the data irreparably compromised by signal artifact of unknown origin. Based on large standard deviation and confidence interval results from mechanical and human testing, even data that appeared "artifact-free" lacked the resolution to differentiate between classic balance paradigms cited in the literature, specifically the difference between standing balance parameters in young and elderly individuals.

In addition to the results mentioned above, the IsoBalance system received a letter of warning in November 2007 (warning letter no. 2008-NOL-09, Appendix C) from the United States Food and Drug Administration (FDA) based on lack of proper clearance for marketing the IsoBalance system as a medical device, and for non-conformity with regard to " ... Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation ..." At the time of this report (June 2008), to the best of our knowledge, the issues outlined in the letter have not been resolved.

The utility of any piece of equipment used in the assessment of human performance is a function of the equipment's accuracy, or its ability to measure what it is

intended to measure; its precision, or ability to produce consistent results on repeated trials in similar conditions; and its ability to be free from error. Error, in turn, may be systematic or random and adversely affect the device's accuracy or precision, respectively. Additionally, the efficacy of a clinical device lies in its ability to adequately differentiate normal from abnormal states. That is, the estimate of the device must represent the characteristic being measured and the estimate must be sensitive to differences or changes in the state of the characteristic.

When assessing postural sway, a device should be able to accurately estimate changes in the COP, provide reproducible results when testing the same subjects under similar conditions, and be free of non-biological signals that interfere with estimates of biological change. Additionally, estimates of interest should represent the underlying biological characteristic that one is attempting to measure (i.e., postural stability) and be able to differentiate changes in postural stability within and between individuals. The current study evaluated the performance of the IsoBalance system in measuring COP in a lab setting and postural sway in a field setting. The IsoBalance performed marginally at best under systematic scrutiny.

MECHANICAL TESTING

The Load Test was performed within a reasonable physiological range for weight (90-180 lbs) and measured consistently within these ranges using calibrated weights (within 2 to 4 lbs. across platforms) for most trials. However, there was a substantial divergence in recorded mass compared to actual mass in approximately 1 out of every 9 trials. In trials when errors in recorded mass were present, the estimation from the IsoBalance ranged from 11% to 24% of the target weight. For an applied weight of 180 lbs, this equates to a measurement error of ± 20 to 43 lbs. Given that the intent of the IsoBalance is to be used to assess postural stability of Soldiers exposed to blast, the rate and magnitude of this error is unacceptable and has the potential to generate large amounts of inaccurate data and potentially result in inappropriate dispositions for Soldiers exposed to blast.

The Point Test revealed upper boundary 95% CI differences of up to 0.13 inches from measurements taken near the origin, and up to 0.33 inches from a reference point in each quadrant, with coefficients of variation ranging from 29%-79%. Results of these repeated measurements demonstrated findings similar to those found in the lab, which suggest that the COP positional accuracy of the machine decreases as measurements are taken away from the origin. Ideally, all points would be off by similar magnitudes and in the same direction to the reference, as seen in point 1 (closest to the origin, Figure 4). Clearly, however, this is not the case, and the within-point variability was much higher in points that were located away from the origin. This point variability translates to a decreased confidence regarding the accuracy of a point placed at these locations.

Two potential reasons for the magnitude of the variability recorded in this study follow: 1) The IsoBalance software display reported the COP with a resolution of 0.1

inch (2.54 mm), whereas similar devices cited in the balance literature report values with a resolution of 0.04 in (0.1 mm). 2) The device used in the field to apply pressure to the platforms had a contact area of approximately 4 mm, which could be considered a limitation. However, these calibration devices (i.e., garden stakes) were readily available and sufficiently rigid to provide appropriate COP measurements for a study in the field.

It is not possible to determine the exact magnitude of an individual artifact spike, because access to the raw time series data from the system was not available. However, we observed drastic changes in COP position and excursion while performing calibrated load tests with weights (inanimate, stationary objects). As evidenced in Figures 6 through 8, displacement and excursion measurements were more severely affected by the presence of artifact than were estimates of the percentage of time an individual's mean COP was maintained in an area of a given diameter. Similarly, as the diameter of these areas increased, the influence of artifact was less profound. These findings illustrate two important limitations of the IsoBalance system. First, the consistent appearance of artifact invalidates the IsoBalance device as an assessment tool for postural sway, because one is not able to accurately assess COP displacement or excursion. Additionally, the end user does not have the ability to access the raw time series data to eliminate data points that are artifact.

The second issue relates to the ability of the 0.6 in circles to serve as an appropriate estimate of postural stability. As stated previously, postural stability is the ability to maintain the COG within the BOS. Therefore, postural instability occurs when the COG travels outside the BOS due either to excessive changes in COG magnitude or velocity. The IsoBalance does not provide COP velocity data and, therefore, it is not possible to determine whether the 0.6 in circle parameter is reflective of this variable. However, the fact that artifact drastically increased the magnitude of displacement and excursion errors without a concomitant change in the 0.6 in circle suggests that these variables are not strongly associated. Indeed, our regression analyses in artifact-free data support this hypothesis. These data clearly demonstrate that the 0.6 in circle is unable to accurately predict either displacement or excursion estimates.

The test-retest reliability of the IsoBalance COP measurements was generally unacceptable for clinical standards. These findings are not surprising, however, as reports of the reliability of COP parameters assessed during single trials tend to be low. We were unable to find previous reliability studies for each position we tested; however, several studies have evaluated one or more of the positions utilized in the current study and provide adequate comparisons. LaFond et al. (15) reported on the reliability of COP parameters in healthy elderly individuals during 3 trials at each of 3 trial durations (30, 60, and 90 sec) in normal quiet stance. These authors found ICC (2,1) estimates of .29 to.52 for A/P COP displacement and .44 to .62 for M/L COP displacement, with longer duration trials yielding improved reliability estimates. Doyle et al. (5) reported ICC (2,1) estimates of .43 and .71 for A/P and M/L displacement, respectively, during three 10-sec trials of quiet stance with eyes open and .65 and .51 for A/P and M/L displacement, respectively, during quiet stance with eyes closed in young healthy men and women.

Clinical instrument reliability is a function of both the variability associated with the instrument and biological variability in the population of interest. While the ICC provides an index of relative reliability, it is limited in that it cannot dissociate instrument from biological variability. In order to more accurately delineate these sources of error, we also calculated coefficients of variation (CV), which is the ratio of within subject variability to the mean score for that device. In other words, it is the error associated with the measurement on repeated testing, expressed as a percentage of the mean score. Typically, a difference score (either between trials or between individuals) must exceed the CV in order to be considered a relevant change (one not associated with measurement error). Doyle et al. (5) reported CV of 39% and 24% for measures of A/P displacement and of 32% and 37% in M/L displacement in young healthy individuals during trials of normal quiet standing with eyes open and closed, respectively. Geurts et al. (6) reported similar results (29% A/P and 35% M/L eyes open; 27% A/P and 32% M/L eyes closed) in young healthy subjects during three 20-sec balance trials. These statistics are much lower than those calculated for similar conditions in the current study (54% and 80% A/P displacement; 42% and 46% M/L displacement).

Even COP data without artifact did not compare favorably to similar studies in the open literature. In a study that investigated how young and older healthy adults adapt to balance tasks of increasing difficulty, Amiridis et al. (1) asked participants to stand on a Kistler force platform in normal quiet standing (NQS) and Romberg-sharpened (Tandem) postures. Maximum COP ranges in the medio-lateral (M/L) and antreo-posterior (A/P) directions were compared between groups and across conditions. Significant differences ($p \leq 0.05$) were noted between younger adults (YOUNG: $n = 20$; mean age 20.1 ± 2.4 [SD] years) and older adults (OLD: $n = 19$; mean age 70.1 ± 4.3 years), which demonstrated that the older adults had significantly greater COP A/P excursion than the younger adults. The largest significant difference between YOUNG and OLD groups was observed during the NQS condition, during which the OLD group demonstrated greater A/P COP range (21.8 ± 10.9 mm) than YOUNG (6.8 ± 1.3 mm). During NQS the OLD group also demonstrated greater A/P COP excursion (4.7 ± 1.2 mm) than YOUNG (3.2 ± 1.0 mm). Further significant differences were observed for both age groups between NQS and Tandem postures. Table 20, which has been converted to inches for direct comparison with the IsoBalance results, summarizes these findings. Similar mean COP ranges have been reported by Panzer et al. (18), with mean a COP A/P range of 0.31 inches (7.5 mm) and COP M/L range of 0.26 inches (6.3 mm) reported in subjects ($n = 24$) during NQS.

To facilitate comparison of our data to current literature, data were analyzed only for subject's whose complete battery (all tests) were artifact free ($n = 60$). The results (mean, SD, and 95% CI) of these subjects were compared to the data from the "YOUNG" group from Amiridis et al. for both quiet and tandem standing in Table 20. Two general trends are noteworthy when comparing data between these two studies. First, the means reported in our data were much larger than those data reported by Amiridis et al. (1) for comparable positions in comparably aged subjects. Secondly, the standard deviations from the current study are larger than the means reported for comparable foot positions by Amiridis et al. (1) Both of these points lead us to question

the utility of the IsoBalance for testing standing balance, as compared to other similar equipment used in the literature to measure the same variables, when so much variability is present in the artifact-free data from the current study. In fact, we suggest that the IsoBalance platform may have a lower resolution than is required to measure differences between young and older healthy subjects, let alone to quantify differences between those with and without TBI.

Table 20. Center of Pressure (COP) Excursion From Standing Balance Literature. Mean (± SD) Maximum Range of COP Anterior-Posterior (A/P) and Medial-Lateral (M/L) Excursions for normal quiet standing (NQS) and Tandem stance foot positions. " * " indicates significant differences ($p \leq 0.05$) between age groups; "#" indicates significant differences between foot positions within age group. Modified and converted to inches from Amiridis et al. (2003)

foot position	measurement (inches)	OLD	YOUNG
NQS	CoPmax A/P	0.19 +/- 0.05	0.13 +/- 0.04 *
	CoPmax M/L	0.12 +/- 0.03	0.10 +/- 0.03
Tandem	CoPmax A/P	0.51 +/- 0.46 #	0.22 +/- 0.06 * #
	CoPmax M/L	0.34 +/- 0.15 #	0.19 +/- 0.03 * #

Table 21. Comparison of Data Collected at Ft. Jackson to Data Reported in the Literature. All data are reported in inches. Data for current study represent artifact-free data (n = 60). Tandem standing data from current study represents average data from TSRLEO position only (Tandem Standing, Right in front of Left, Eyes Open).

Global Variable	Source (variable)	QUIET STANDING		TANDEM STANDING	
		Mean (SD) (inches)	95% CI	Mean (SD) (inches)	95% CI
Max A/P excursion	Current study (dif X)	0.21 (0.16)	0.17 – 0.25	0.70 (0.65)	0.65 – 0.91
	Amiridis *et al.* (1) (CoPmax A/P)	0.13 (0.04)	0.11 – 0.15	0.22 (0.06)	0.19 – 0.25
Max M/L excursion	Current study (dif Y)	0.50 (0.28)	0.43 – 0.57	0.86 (0.97)	0.97 – 1.29
	Amiridis *et al.* (1) (CoPmax M/L)	0.10 (0.03)	0.09 – 0.11	0.19 (0.03)	0.18 – 0.20

Amiridis et al. (1) (n = 20)

CONCLUSIONS

Overall, the IsoBalance performed poorly when tested for its intended use. In addition to being non-compliant with Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) as defined by the FDA (FDA warning letter 2008-NOL-09, Appendix C), estimates of position and force recorded in a laboratory setting under stringent control yielded inconsistent estimates of both (Appendix B). Repeated measurements of mechanical performance in a field setting demonstrated substantial variability in measurements and large errors in estimates of position and force. The utility of the device was undermined by the presence of non-biological signaling error in a large preponderance of tests that impeded accurate estimation of COP changes in healthy subjects. The reliability of artifact-free data obtained from human subjects performing repeated testing was inadequate to warrant the use of this device in a clinical setting as a means of determining postural stability. Errors in estimation due to measurement variability during repeated testing exceeded acceptable levels for most measurements of COP displacement and excursion. The percentage of time a subject's COP was maintained in a 0.6 in area about their average COP for a trial demonstrated poor to marginal ability to predict changes in COP excursion or displacement, with the exception of frontal plane displacement. Coupled with the poor reliability associated with this metric, it is not an appropriate measurement of postural stability in any population. The IsoBalance system's ability to estimate changes in the COP, compared to similar studies in the literature, is wanting and further limits its utility to assess postural stability in Soldiers.

RECOMMENDATIONS

1) In order to assist medical providers and commanders on the battlefield in identifying and classifying Soldiers with mTBI, systematic evaluation of measurements and indices of postural stability are needed. These evaluations should be based on existing scientific evidence and should seek both to bridge knowledge gaps in evidence and develop field ready, quantifiable techniques to assess postural instability in Soldiers with mTBI.

2) The causes of the IsoBalance system artifact observed in this study need to be identified, and steps must be taken to prevent its future occurrence. We were unable to isolate a specific cause of the artifact; however, there are a number of possible causes that should be systematically checked to identify it. These include but are not limited to 1) electrical interference, 2) interference related to movement on the force plate, 3) signal disruption during analog to digital conversion, 4) movement artifact related to sampling rate of method, or 5) signal processing errors during post-processing.

3) A single measurement of balance is inadequate to assess postural stability. We believe that the low reliability associated with the variables of interest in this study

was related both to the measurement instrument as well as to the method of testing (i.e., a single trial of balance testing). This supposition is supported in the literature and may be due to the unstable nature of postural sway in and of itself, or may be due to learning effect associated with novel tests of balance such as tandem stance (5, (15, (16). We performed a single trial of balance in the current study in order to assess the accuracy and precision of the IsoBalance as a rapid assessment tool in a field setting. It is strongly recommended that future protocols that incorporate postural stability testing either provide practice sessions for a given condition until a stable measure can be obtained, or plan to conduct multiple iterations of a given test condition that can then be averaged to minimize error inherent to the measure.

4) A rapidly quantifiable, field expedient metric that accurately identifies postural instability in Soldiers following a blast injury or fall should be systematically developed. Clarify phrasing/punctuation ...While a single metric, such as the percentage of time COP is maintained in a .6 inch area about the mean COP for a trial, is appealing in its ability to be easily quantified and assessed, such a metric must be reproducible and have a strong and direct relationship to the characteristic of interest (postural stability). Further testing to identify such a metric is needed.

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APPENDIX A: PARTICIPANT INTAKE SURVEY

SUBJECT ID#:_____

In this survey we will ask you for information about your personal and medical history. This survey should take no more than 15 minutes for you to complete. All efforts will be made to keep your personal information confidential. We do not need your name or social security number on any part of this survey, and you will not be identifiable by name or description in any publications about this study. Taking part in this study is completely voluntary.

PART A: BACKGROUND INFORMATION

1. **How old are you?** _____

2. **What is your Gender?**
   - ☐ Male
   - ☐ Female

3. **What is your ethnic background?**
   - ☐ Caucasian
   - ☐ African American
   - ☐ Hispanic
   - ☐ Asian
   - ☐ Latin American
   - ☐ Other _____

4. **How long have you been in military service?** _____years _____months

5. **What is your MOS?** _____

6. **Are you:** ☐ Active Duty
   ☐ National Guard
   ☐ Reserve

7. **Did you receive a medical waiver to enter the Army?**
   ☐ Yes ☐ No
   If yes, for what medical condition?
   _____

8. BEFORE JOINING THE ARMY, did you ever experience or were you ever told that you had any of the following:

			If YES, how many times?				
			1	2	3	4	5 or more
Head Injury	☐ Yes	☐ No	☐	☐	☐	☐	☐
Loss of consciousness less than 1 minute	☐ Yes	☐ No	☐	☐	☐	☐	☐
Loss of consciousness from 1 to 20 minutes	☐ Yes	☐ No	☐	☐	☐	☐	☐
Loss of consciousness more than 20 minutes	☐ Yes	☐ No	☐	☐	☐	☐	☐
Vehicle accident (any type of vehicle)	☐ Yes	☐ No	☐	☐	☐	☐	☐
Exposure to Blast (IED, mortar, etc.)	☐ Yes	☐ No	☐	☐	☐	☐	☐

9. Did you ever experience or were you ever told that you had any of the following?

			If YES, how many times?				
			1	2	3	4	5 or more
Broken bones (describe):_____ _____ _____)	☐ Yes	☐ No	☐	☐	☐	☐	☐
Sprains/strains *within past month* (describe): _____ _____)	☐ Yes	☐ No	☐	☐	☐	☐	☐
Ear or other infection that might affect your balance (describe): _____ _____ _____)	☐ Yes	☐ No	☐	☐	☐	☐	☐
	☐ Yes	☐ No	☐	☐	☐	☐	☐
	☐ Yes	☐ No	☐	☐	☐	☐	☐
	☐ Yes	☐ No	☐	☐	☐	☐	☐

10: Are you currently taking any over-the-counter medications?

☐ Yes (type & dose):

_____

☐ No

11: Are you currently taking any prescription medications?

☐ Yes (type & dose):

_____

☐ No

APPENDIX B: ISOBALANCE MECHANICAL PILOT TESTING

(Joseph Seay, Ph.D., Peter Frykman, M.S., CPT Mark E. Lester, PT, DPT, OCS)

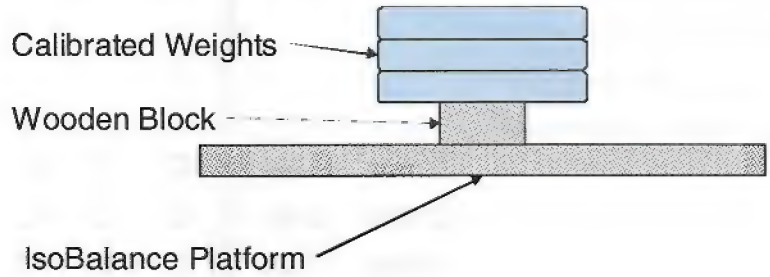
METHODS

Of the 16 platforms shipped to USARIEM to be used in testing, four platforms (25%) were randomly selected and taken to the biomechanics lab for mechanical reliability and validity testing.

Load Test

A Load Test (Fig 17) was developed to determine the accuracy and precision of the IsoBalance platforms in measuring a vertical load applied to their surface. Two wooden interlocking 4 in x 4 in blocks, 10 inches in length, were centered on the platform during testing to allow convenient application and removal of the weights. Force plates were zeroed between each trial with the wooden blocks in place to negate the weight of the blocks. Once the force plate was zeroed, a known mass was applied to it using calibrated weights. A 30-sec trial was then performed on the system with the load in place. Systems were incrementally loaded on successive trials with masses of 20.5 kg, 40.8 kg, 61.3 kg, 81.9 kg, 102.4 kg, 122.5 kg, and 142.9 kg.

Figure 17. Graphic depiction of the load test. Weight was increased between trials, and the platform was "zeroed" between trials with the wooden block in place.



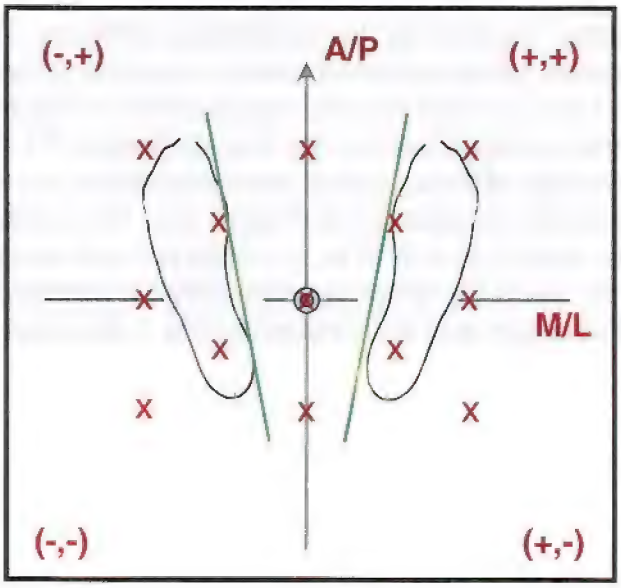
Point Test

A point test was developed to determine the accuracy and precision of the IsoBalance platforms in measuring centers of pressure (COP) at the origin and at 12 known distances from the origin of the platform. This was accomplished by setting up a grid, the boundaries of which encompassed a person with a U.S. size 12 men's shoe standing on the platform in the position that is outlined in the manual (medial malleoli directly superior to the intersections of the black and

green lines, with medial heel and forefoot just lateral to the green lines on their respective sides [see Figure 18]). This resulted in a testing area 17.5 in wide (M/L direction) by 11.88 in long (A/P direction) (approx 44 x 30 cm). A template was created that allowed us to measure several points within this area (13 points including the origin), and this template was applied to all platforms being measured. The points are marked in Figure 18, and the dimensions and sign convention of these points are given in Table 23. At each point on the template, a calibration device with end point area of less than 0.2 cm^2 was applied to each point indicated in Figure 18, and X (medial/lateral) and Y (anterior/posterior) coordinate data were recorded from the software at each point on all platforms. All points recorded from the IsoBalance software were compared with physically measured points obtained using a measuring tape (Table 23). 13 points were measured and marked on the force plate, vertical pressure was applied to each point, and device readings were recorded.

Results are reported with respect to a Cartesian (X, Y) displacement from the origin, where X represents medial/lateral (M/L) displacement and Y represents anterior/posterior (A/P) displacement of the COP. Further, anterior displacement of the COP relative to the origin is indicated by a positive X value (+X, Y), and posterior displacement of the COP is indicated by a negative X value (-X, Y). COP displacement to the right of the origin is indicated by a positive Y value (X, +Y), and COP displacement to the left of the origin is indicated by a negative Y value (X, -Y). Sign conventions are displayed visually in Figure 18. Means and standard deviations were reported for all points across the four platforms tested.

Figure 18. Depiction of subject foot placement on the IsoBalance Platform from coronal view of the platform. Subject medial malleoli are vertically aligned over the horizontal grey line (M/L axis), and medial aspect of the subject's feet were to be aligned with the green lines as shown. Each "X" marks a point of measurement for the point test.



RESULTS

Load Test

The individual platform and aggregate results of the Load Test are shown in Table 22. The measured weight between all four platforms varied from as little as 0.2 lbs (0.09 kg) to as much as 0.8 lbs (0.36 kg) between platforms. There was good between-platform consistency, with values ranging within 1 lb across all platforms for any given weight, which equated to less than a 2% difference between platforms for a given weight.

Table 22. Data From Load Test (Test #1). Platforms Are Numbered P1 Through P4, And All Available Data Are Reported In Pounds (lbs). Range And Average Values Were Calculated Based On Recorded Values From P1-P4 Data Only.

Calibrated Weight (lbs)	Platforms Tested				Average (P1-P4)	Range (P1-P4)
	P1	P2	P3	P4		
45.1	44.4	45.0	45.0	44.6	44.8	0.6
89.8	89.0	89.0	89.2	89.0	89.1	0.2
134.9	135.0	134.6	135.0	134.2	134.7	0.8
180.2	179.8	180.0	180.0	180.0	180.0	0.2
225.3	225.0	225.0	225.4	225.6	225.3	0.6
269.5	269.2	268.8	269.4	269.8	269.3	1.0
314.4	314.0	314.0		314.2	314.1	0.2

Point Test

Point coordinates reported by the IsoBalance software were compared with physically measured points obtained using a measuring tape. Results of this test are displayed in Table 23 and visually represented in Figure 19. The measured points were averaged across the four platforms (P1-P4) for each of the 13 points, and the average of these points were presented, as well as the between-platform variance for each point (Figure 20). The between-platform variability was low for point 5 (x = 0.09 in, y = 0.05 in.) and ranged up to considerably higher for point 13, which demonstrated a between-platform SD of 0.24 inches in the X direction and 0.75 inches in the Y direction.

Table 23. COP Point Force Application Test For Four IsoBalance Platforms (P1-P4), As Compared To A Hand-measured Standard ("measured"). All Data Are Reported In Inches (in).

Point	Measured		Plat #1		Plat #2		Plat #3		Plat #4		Mean (P1-P4)		SD (P1-P4)	
No.	X	Y	X	Y	X	Y	X	Y	X	Y	X	Y	X	Y
1	**-7.56**	**6.75**	-6.95	5.45	-7.15	5.75	-7.95	6.35	-7.4	5.75	**-7.40**	**6.08**	0.43	0.38
2	**0.00**	**6.75**	-0.45	6.15	-0.65	6.25	-0.55	6.25	-0.5	6.1	**-0.41**	**6.35**	0.09	0.08
3	**7.75**	**6.75**	6.55	5.65	6.25	5.75	6.25	5.65	6.7	6.2	**6.70**	**5.95**	0.23	0.26
4	**-7.56**	**0.00**	-7.65	-0.55	-7.9	-0.45	-7.95	-0.45	-7.8	-0.62	**-7.77**	**-0.36**	0.13	0.08
5	**0.00**	**0.00**	-0.45	-0.65	-0.65	-0.65	-0.55	-0.55	-0.5	-0.6	**-0.41**	**-0.46**	0.09	0.05
6	**7.75**	**0.00**	7.05	-0.65	6.75	-0.65	7.0	-0.65	6.75	-0.6	**7.14**	**-0.49**	0.16	0.03
7	**-7.56**	**-4.75**	-7.65	-5.35	-7.75	-5.25	-7.65	-5.05	-7.8	-5.4	**-7.65**	**-5.10**	0.07	0.15
8	**0.00**	**-4.75**	-0.45	-5.45	-0.65	-5.4	-0.65	-5.35	-0.6	-5.5	**-0.44**	**-5.24**	0.09	0.06
9	**7.75**	**-4.75**	6.55	-5.15	6.45	-5.2	6.85	-5.35	6.35	-5.5	**6.90**	**-5.11**	0.22	0.16
10	**-3.75**	**3.75**	-4.15	3.25	-4.25	3.35	-4.25	3.25	-4.2	3.2	**-4.10**	**3.40**	0.05	0.06
11	**3.75**	**3.75**	3.35	3.15	2.95	3.15	3.05	3.25	2.9	3.15	**3.28**	**3.33**	0.20	0.05
12	**-3.75**	**-3.75**	-4.1	-4.45	-4.25	-4.25	-4.15	-4.35	-4.15	-4.1	**-4.06**	**-4.20**	0.06	0.75
13	**3.75**	**-3.75**	3.45	-4.55	2.95	-4.25	3.15	-4.35	2.95	-4.15	**3.33**	**-4.23**	0.24	0.75

Figure 19. IsoBalance Point Test individual data points. Visual comparison of individual point data (pt 1-13) for four platforms (Plat #1 - 4) compared to data measured by hand ("measured", indicated by dark diamonds).

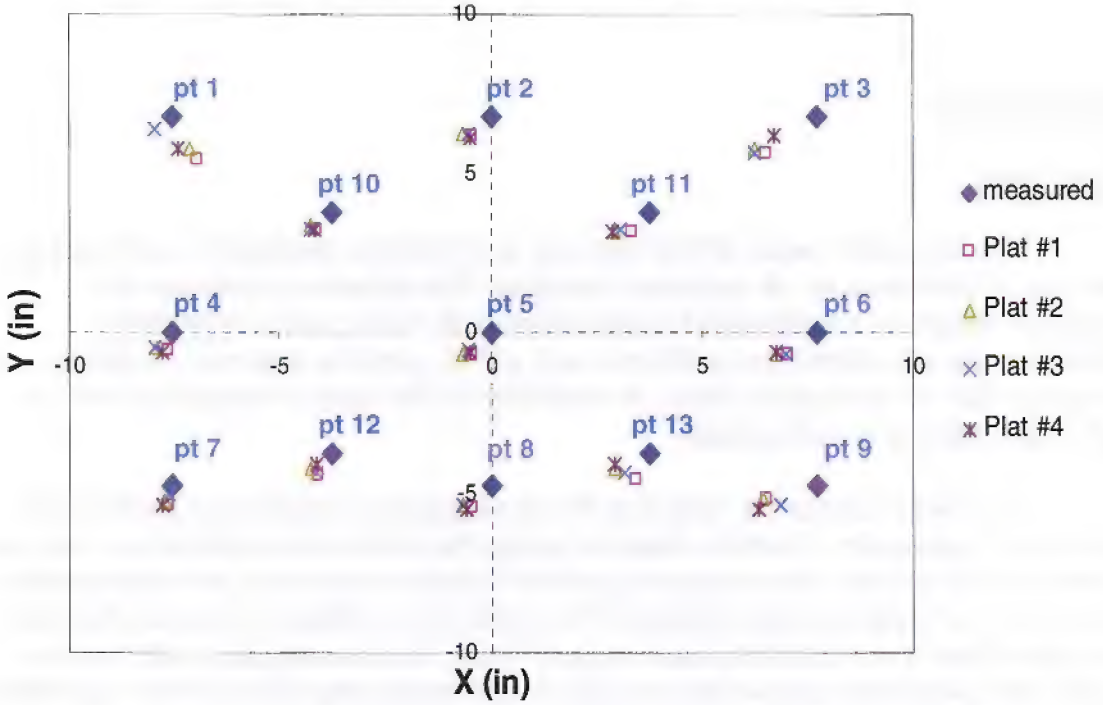
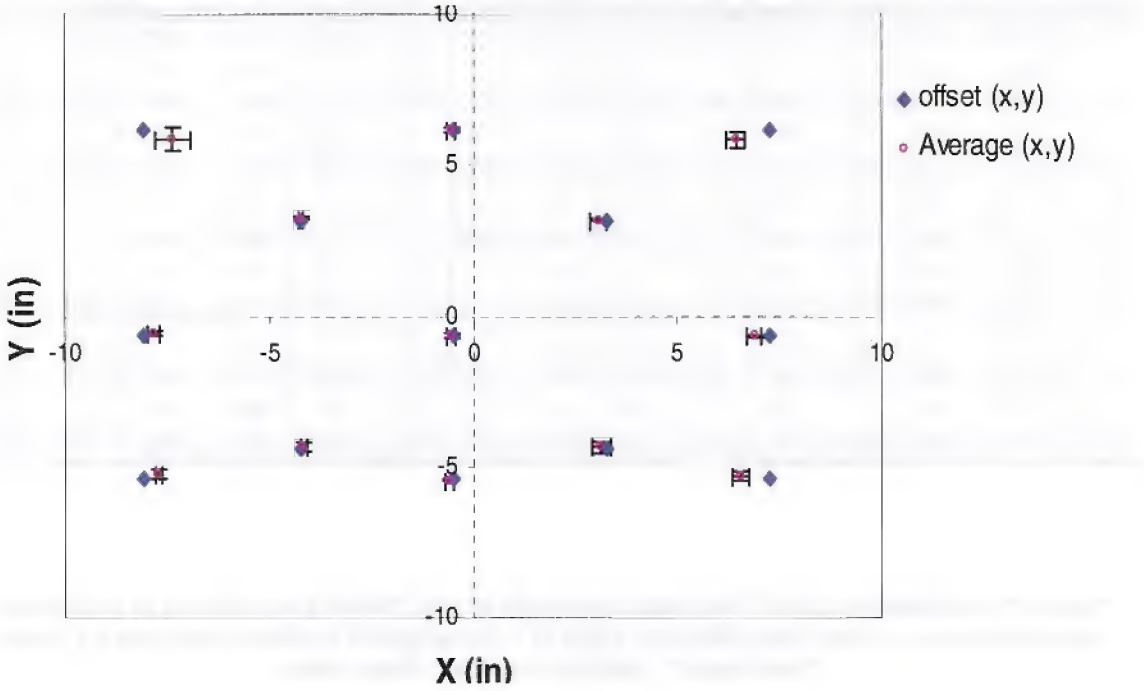


Figure 20. IsoBalance Point Test averaged data across platforms. Each point measurement is an average of measured points across each point (Average) compared to the adjusted measured data (Offset). Offset data are based on mean difference between measured origin and average origin for all four platforms. Error bars represent 1 SD in both X and Y directions, from the values presented in Table 23.



DISCUSSION

Load Test

The expected result of this test was a consistent reading for each weight among all platforms for all calibrated weights. The difference between the average weight and calibrated weight columns in Table xxx is acceptable (deviation for all weights on platforms was < 2%), and the between-platform range is also an acceptable level of variability for the type of measurement for which this device is being used.

It is also important to note that the investigators would have preferred to perform a hysteresis to test for linearity using the loads mentioned above, as this is standard practice when evaluating similar devices. However, we were unable to perform a hysteresis test because the IsoBalance software required the user to reset ("zero") the platform after every 2nd trial. The investigators felt that the Load Test performed above did provide a reasonable depiction of the capabilities of the IsoBalance platform system with respect to measuring weight.

Point Test

At first observation, one observes that none of the platform measurements (Plat #1 - 4) coincide with the measured data (diamonds, Figure 19) at any point. This discrepancy poses no threat to accuracy or validity of measurements, as long as the between-platform measurements demonstrate little variability, as can be observed with the measurements at points 2, 5, and 8 (Figure 20).

Of concern, however, is the low between-platform measurement consistency (high variability) at most other points on the platform, where the average location of the COP relative to the measured points and the variability in range are much different than points 2, 5, and 8 for all platforms. Of particular concern are points 1, 3, and 9, which represent three corners of the outer limits of potential physiological measurements.

The main concern when interpreting test data at these points is the difference that exists between location of the average and variability between points on the platforms. For example, the measured points at the platform origin (point 5) demonstrate different average locations (relative to their references) and variability than the outer points on the platform (points 1, 3, 7, and 9, Figure 20). For example, in Figure 19, the reader can observe that the individual points measured relative to the platform origin (point 5) are clustered tightly below (-Y) and to the left (-X) of the reference point, indicated by the dark-filled diamond. By comparison, the points recorded around the upper left corner of the platform (point 1, Figure 20) are not as tightly clustered and are located, on average, below (-Y) and to the RIGHT (+X) of the reference point. In fact, when all other points recorded are compared to adjusted reference points based on the average distance of the clusters relative to point 5 ("offset," Figure 20), one can observe that not all points are clustered relative to that reference, nor are they clustered with the same variability. As a result, instead of being able to apply one correction factor to all points, any correction factor applied to these data would have to be formulated on a point-by-point basis. The overarching concern in interpreting these data is that this "non-linear" adjustment could ultimately adversely affect the COP measurements, which represents a weighted average of all vertical force being applied to the platform.

CONCLUSIONS

The Load Test demonstrated acceptable between-platform differences. However, the Point Test demonstrated unacceptable variability between 13 points within and across four platforms. While the magnitude of this variability in and of itself was cause for concern with regard to the integrity of this measuring device, of greater concern was the difference between orientations of these points (i.e., the *direction* of the difference was not consistent, even within the

same platform). Differences between the adjusted theoretical standard and each platform at times exceeded one inch (> 25mm), which is extremely poor consistency when other products designed for measuring balance in humans are measuring between-platform differences on the order of 5-10 mm. Within-platform errors were non-linear in both magnitude and orientation from the standard, which implies that there is not a linear correction factor that can be applied, even within the same platform.

As a result of these preliminary findings, we felt that further testing was warranted incorporating all IsoBalance systems. We therefore undertook mechanical testing of all systems daily over 6 days while simultaneously conducting a field study of postural sway in humans. The field-based mechanical testing included a 3-load and 5-point test performed prior to human testing each day as a means of system calibration on all platforms. The methodologies and results of these tests are described in detail in the main body of this report.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200 – Suite 500
Nashville, TN 37217

Telephone: (615) 366-7801
FAX: (615) 366-7802

March 20, 2008

WARNING LETTER NO. 2008-NOL-09

FEDERAL EXPRESS
Delivery Signature Requested

Mr. Eric J. Johnson, Owner
Acacia Engineered Products, LLC
1108 Harpeth Industrial Court
Franklin, Tennessee 37064

Dear Mr. Johnson:

On October 11 and 17, 2007, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, located at 1108 Harpeth Industrial Court, Franklin, Tennessee and determined your firm manufactures the IsoBalance. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 United States Code (USC) 321(h)], this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

Our inspection and a review of our records revealed the IsoBalance is adulterated under Section 501(f)(1)(B) of the Act [21 USC 351(f)(1)(B)], because you do not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) of the Act [21 USC 360e(a)], or an approved application for an investigational device exemption (IDE) under Section 520(g) of the Act [21 USC 360j(g)]. The device is also misbranded under Section 502(o) the Act [21 USC 352(o)], because you did not notify FDA of your intent to introduce the device into commercial distribution, as required by Section 510(k) of the Act [21 USC 360(k)]. For a device PMA, the notification required by Section 510(k) of the Act [21 USC 360(k)], is deemed satisfied when a PMA is pending before the agency as required under Title 21, *Code of Federal Regulations*, Part 807.81(b) [21 CFR 807.81(b)]. The kind of information you need to submit in order to obtain approval or clearance for your device is described on the internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

The IsoBalance also is misbranded under Section 502(o) of the Act [21 USC 352(o)], because the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the Act [21 USC 360]. In addition, your device was not included in a list required by Section 510(j) of the Act [21 USC 360(j)].

This inspection also revealed your device is adulterated within the meaning of Section 501(h) of the Act [21 USC 351(h)], because the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at 21 CFR 820. Since your firm has failed to establish or implement the QS procedures required by Part 820, your device is in violation of these regulations.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, PMA applications for Class III devices to which the QS regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

This letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483, issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations to bring your products into compliance.

Your response should be sent to Cynthia R. Gibson, Compliance Officer, U.S. Food and Drug Administration, at the above address. If you have any questions about the content of this letter, please contact Ms. Gibson at (251) 344-8208, extension 105.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483